IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA and THE STATE OF TENNESSEE *ex rel.* SUZANNE ALT, MARY BUTNER, DANA BROWN, JENNIFER PRESSOTTO, JUNE KIMBROUGH, SCOTT STEED and ALLISON CHANCELLOR,	)	
Plaintiffs,	)	Case No.: 3:16-cv-00549 JUDGE TRAUGER
v.	)	
ANESTHESIA SERVICES ASSOCIATES, PLLC, d/b/a COMPREHENSIVE PAIN SPECIALISTS; PETER B. KROLL, M.D.; JOHN DAVIS; STEVEN R. DICKERSON, M.D., GILBERTO A. CARRERO, M.D. and RUSSELL S. SMITH, D.C.,	)	**JURY TRIAL**
Defendants.	)	

CONSOLIDATED COMPLAINT IN INTERVENTION

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I. INTRODUCTION

1. The United States of America and the State of Tennessee bring this action under the False Claims Act, 31 U.S.C. § 3729, *et seq*. (the "FCA"); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182 to -185 (the "TMFCA"), the Federal Priority Statute, 31 U.S.C. § 3713, and common law theories of payment by mistake, unjust enrichment and fraud against Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists ("CPS"), Peter B. Kroll, M.D. ("Kroll"), John Davis ("Davis"), Steven R. Dickerson, M.D. ("Dickerson"), Gilberto A. Carrero, M.D. ("Carrero") and Russell S. Smith, D.C. ("Smith") (collectively, "Defendants") to recover over $50 million in damages suffered as a result of Defendants' various unlawful conduct, including the submission of thousands of false claims to federal and state funded health care programs. Defendants' actions unjustly enriched their bank accounts at the expense of the United States, the State of Tennessee and the tax-paying public, as set forth in detail below.

2. CPS operated pain management clinics across twelve states with, at one time, over sixty locations, and a principal office and two testing facilities located in Williamson County, Tennessee.

3. The main physician-owners of CPS -- Dickerson, Carrero, and Kroll (the "Owners") -- implemented and approved CPS's policies, including providing the company's Chief Executive Officer, Davis, now a convicted felon, with the authority to oversee the day-to-day operations of the company. For over six years, the Owners and Davis used CPS as a mechanism to obtain the maximum amount of reimbursement allowed from Medicare, TRICARE, Medicaid and CHAMPVA/Choice (collectively, the "Federal Health Care Programs") and TennCare, with each CPS patient representing a billing opportunity, regardless of whether the care was medically necessary or the claim submitted was accurate.

4. Davis and the Owners profited tremendously from the implementation of a policy to order myriad urine drug testing on virtually every CPS patient on virtually every visit. While such testing may be approved as a diagnostic tool, rather than determine need on an individualized basis, CPS, through Davis and with the backing of the Owners, adopted a practice of testing urine through a "standing order" that did not take into account patient risk levels and included non-reimbursable specimen validity testing, duplicative testing for the same types of drugs, and an automatic, secondary test to determine the quantity of drugs present, regardless of whether the urine tested positive for drugs. This testing was commonly referred to as "liquid gold" – leaving no doubt that profit was Defendants' primary objective in performing urine drug testing.

5. Indeed, the Federal Health Care Programs paid CPS over $10 million for quantitative drug testing performed from 2016 to 2018 alone.

6. CPS then expanded its unlawful testing policies to include submitting claims for genetic blood testing and psychological testing, for which the Federal Health Care Programs and TennCare should not have reimbursed, as it did not satisfy the express requirements for payment and was not otherwise medically necessary.

7. From the outset, Davis adopted, and the Owners had knowledge of, CPS's bonus program, which incentivized mid-level providers to order UDS testing, genetic testing, Health and Wellness panels, and psychological testing, as well as other ancillary services, including durable medical equipment ("DME").

8. Davis also entered into an agreement for CPS to take over operations for a clinic in East Tennessee that Smith, a chiropractor, had previously owned. Smith continued to oversee this clinic and then two others, but he did not personally treat any patients at CPS. For his services, he was entitled to receive 94 percent of revenues generated from the Cleveland, Tennessee clinic, as

well as substantial revenues from the others. To ensure that revenues were high, Smith asserted pressure on the providers at his clinics, which resulted in unnecessary medical services and devices, including excessive and unnecessary urine and blood testing and ordering of DME.

9. To make certain that no potential revenue opportunity was lost, Davis also engaged in a practice referred to as "upcoding," whereby he would alter the codes submitted by providers for their claims to maximize the amount of reimbursement he could seek from the Federal Health Care Programs and TennCare.

10. In late 2013, Davis also implemented a plan to bill the federal and state health care programs for non-reimbursable acupuncture, of which the Owners were aware and for which they were responsible for submitting false claims. Even when CPS's compliance personnel confirmed that billing for acupuncture was unlawful and calculated the amount of overpayment, neither Davis, nor any of the Owners, returned this money to the United States or Tennessee.

11. Separately, Kroll was responsible for submitting claims to the United States falsely indicating that he was the Rendering Provider. In one particularly egregious example of this fraudulent conduct, Kroll caused over 2,500 claims to be submitted to Medicare, for which CPS was paid almost $350,000 for procedures and testing on patients during a period of time when Kroll was out of the country on vacation.

12. Further, Davis, through his role as the Chief Executive Officer of CPS, entered into a scheme that allowed him to receive kickbacks for referring DME prescriptions of CPS patients to CCC Medical. On April 4, 2019, he was convicted of all counts, including one count of

conspiracy and seven counts of violating the Anti-Kickback Statute. *United States v. Davis*, No. 3:18-00077 (M.D. Tenn. April 4, 2019), Dkt. No. 186.[1]

13. The Owners cannot, however, place the blame solely on Davis, as they directly participated in much of the fraudulent conduct Davis orchestrated through CPS and profited therefrom.

14. Without even including all the damages relating to UDS, the United States and Tennessee suffered well over $1 million in damages just from the false claims the Owners submitted to the Federal Health Care Programs and TennCare from 2011 through 2018, when CPS closed down its operations.

15. Dickerson alone submitted over 750 false claims for specimen validity, genetic and psychological testing, as well as acupuncture, which amounts to well over $4 million in penalties, plus treble damages for the amount of overpayment.

16. Carrero is responsible for approximately 800 false claims for specimen validity, genetic and psychological testing, as well as acupuncture, which amounts to over $4.5 million in penalties, in addition to treble damages for the amount of overpayment.

17. Kroll submitted or caused to be submitted over 15,000 false claims for specimen validity, genetic and psychological testing, acupuncture, and claims for testing, services and procedures for patients he could not have seen because he was out of the country, which amounts to at least $80 million in penalties, without factoring in treble damages for the amount of overpayment.

[1] The United States is not seeking damages based on Davis's criminal conduct. However, the evidence presented at trial is relevant to other unlawful conduct alleged herein.

18. Defendants all were unjustly enriched as a result of the multiple fraudulent billing schemes for which CPS wrongfully obtained money from the United States and Tennessee, and their knowing retention of such monetary benefits would be inequitable under these circumstances.

II. JURISDICTION AND VENUE

19. This Court has jurisdiction over this action pursuant to 31 U.S.C. §§ 3730(a) and 3732, 28 U.S.C. §§ 1331, 1345 and 1367(a), and Tenn. Code Ann. § 71-5-183(a).

20. Venue is proper in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because all Defendants reside in or operate in Tennessee and because a substantial part of the events and omissions giving rise to the claims alleged occurred in this District.

III. PARTIES

21. The United States brings this action on behalf of (i) the United States Department of Health and Human Services ("HHS"), (ii) the United States Railroad Retirement Board ("RRB"), (iii) the United States Department of Defense ("DOD"), and (iv) the United States Department of Veterans Affairs ("VA"). This includes the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs for HHS and the RRB; the Defense Health Agency ("DHA"), which administers the TRICARE program for DOD; and the Veterans Health Administration ("VHA") and the Civilian Health and Medical Program for the VA ("CHAMPVA"), which administer the VA benefits.

22. The State of Tennessee brings this action on behalf of its State Medicaid Program, known as TennCare.

23. Defendant CPS was initially formed as Skyline Services Associates, PLLC, on or about July 11, 2000. CPS is a Tennessee professional limited liability company, which elected to

be governed by the Tennessee Revised Limited Liability Company Act. CPS's principal place of business was in Franklin, Tennessee. It has done business as CPS throughout the relevant time period. After 2011, CPS expanded to over 60 affiliated locations in twelve states, and employed approximately 250 health care providers, who saw approximately 48,000 patients per month. The principal members of CPS are Defendants Kroll, Dickerson and Carrero, as well as Dr. Richard J. Muench ("Muench"), who is not named as a defendant herein. CPS also has minority physician-owners, who had no operating control or seat on the Board of Directors. In July 2018, CPS began dissolution proceedings, sold off its assets, and no longer is operating any of its locations.

24. Defendant Carrero is a medical doctor certified in anesthesiology and pain management, who resides in Nashville, Tennessee. Carrero is licensed in Kentucky, Mississippi, Ohio, Tennessee and North Carolina. He took an ownership interest in and began treating patients at CPS in or about June 1, 2004. He served on CPS's Board of Directors from in or about 2017 to present.

25. Defendant Davis is an individual who resides in Franklin, Tennessee and was the Chief Executive Officer of CPS from on or about May 20, 2011 to on or about June 2, 2017 and had managerial control over CPS at all material times. Davis has no medical training or medical certifications.

26. Defendant Dickerson is a medical doctor certified in anesthesiology and pain management, who resides in Nashville, Tennessee. Dickerson is licensed in Tennessee and Kentucky. He took an ownership interest in and began treating patients at CPS at its inception. He served on the Board of Directors for CPS at all relevant times, and was Chairman, President, at a medical director of CPS at certain times throughout the relevant time period.

27. Defendant Kroll is a medical doctor certified in anesthesiology and pain medicine, who resides in Goodlettsville, Tennessee. Kroll is licensed in Ohio, Alabama, Kentucky and Tennessee, but deactivated from Kentucky on February 5, 2019. He took an ownership interest in and began treating patients at CPS in or about August 1, 2006. He served on the Board of Directors for CPS at all relevant times, was Chairman and President since September 30, 2015, and served as Chief Medical Director from on or about January 2016 until it ceased operating.

28. Defendant Smith is a chiropractor, who resides in Cleveland, Tennessee.

IV. LEGAL AND REGULATORY FRAMEWORK

A. The False Claims Act

29. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly presenting or causing to be presented false or fraudulent claims for payment to the United States and for knowingly making or using false records or statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1), (2); 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B) (as amended).

30. For purposes of the FCA,

> (1) the terms "knowing" and "knowingly"—
> (A) mean that a person, with respect to information—
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
> (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

31. The standard of proof under the FCA is a preponderance of the evidence. 31 U.S.C. § 3731(d).

B. The Tennessee Medicaid False Claims Act

32. The TMFCA provides in pertinent part that a person who:

(a)(1)(A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;

(a)(1)(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program;

…

(a)(1)(D) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the medicaid program;

…

is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than twenty-five thousand dollars ($25,000), adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, compiled in 28 U.S.C. § 2461 note; Public Law 101-410, plus three (3) times the amount of damages which the state sustains because of the act of that person

…

(b) For purposes of this section, "knowing" and "knowingly" mean that a person, with respect to information:

(1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

Tenn. Code Ann. § 71-5-182.

C. The Government Health Care Programs

1. Medicare

33. In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq.*, to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

34. Medicare is administered by CMS, which is part of HHS. At all times relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

35. Medicare provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or injury or to improve a malformed body member. Payment will be provided if medical necessity can be substantiated. Section 1862(a)(1) of the Social Security Act, CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Ch. 16, sec. 20.

36. Medicare only covers services furnished by a nurse practitioner who is authorized to practice by the State where the services are furnished and the nurse practitioner performs such services while working in collaboration with a physician. 42 C.F.R. § 410.75.

37. Collaboration is:

> a process in which the nurse practitioner works *with one or more physicians* to deliver health care services within the scope of the nurse practitioner's expertise, *with medical direction and appropriate supervision* as provided for in jointly developed guidelines or other mechanisms *as provided by the law of the State* in which the services are performed.

Id.

38. The Medicare program consists of four parts: A, B, C, and D. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

39. Medicare Part B covers medically necessary services, including provider visits, diagnostic tools that meet accepted standards of medical practice, procedures, medical supplies and DME.

40. From 2011 to February 25, 2018, Cahaba Government Benefit Administrators, LLC ("Cahaba") was the MAC that administered Medicare Part B claims in Tennessee and Alabama. As of February 26, 2018, Palmetto Government Benefit Administrator, LLC ("Palmetto") became the MAC for Tennessee and Alabama.

41. Throughout the relevant time period, Palmetto also was the MAC for North Carolina and South Carolina, as well as for nationwide Medicare claims for RRB beneficiaries.

42. Further, throughout the relevant time period, CGS Administrator, LLC was the MAC for Part B claims in Kentucky and Ohio; Novitas Solutions, Inc. ("Novitas") was the MAC for Arkansas and Mississippi; National Government Services, Inc. ("NGS") was the MAC for Illinois; and Physician Services Government Health Administrators was the MAC for Indiana, Iowa, Michigan and Missouri.

2. TRICARE

43. TRICARE is a federal health care program that is administered by DHA, a component of DOD. TRICARE provides health care insurance for active duty military personnel, military retirees, and military dependents.

44. TRICARE contracts with one of two contractors, including Humana Government Business, Inc., d/b/a/ Humana Military, to administer the TRICARE program, including the processing and payment of claims for reimbursement of physician and mid-level providers' services from TRICARE.

45. TRICARE requires that appropriate medical records be maintained to substantiate that billed services were actually rendered. 32 C.F.R. § 199.7(b)(3). Failure to document the care billed will result in denial of payment by TRICARE. *Id.*; TRICARE Policy Manual 6010.60-M, Ch. 1, § 5.1, ¶ 3.2.

46. TRICARE has specified examples of fraud or abuse against the TRICARE program as including "[m]isrepresentations of . . . description of services rendered." 32 C.F.R. § 199.9(c).

3. Medicaid/TennCare

47. The Medicaid Program provides funding for medical and health-related services for certain individuals and families with low incomes and virtually no financial resources. 42 U.S.C. § 1396, *et seq*. Those eligible for Medicaid include pregnant women, children, and persons who are blind or suffer from other disabilities and who cannot afford the cost of health care. 42 U.S.C. § 1396d. The Medicaid program is a joint federal–state health care program. 42 U.S.C. § 1396b. If a state elects to participate in the program, the costs of Medicaid are shared between the state and the federal government. 42 U.S.C. § 1396a(a)(2). In order to receive federal funding, a participating state must comply with requirements imposed by the Act and regulations promulgated thereunder.

48. Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 to 71-5-199. The federal government, through CMS, provides approximately 65 percent of the funds used by the Tennessee Medicaid program to provide medical assistance to persons enrolled in the Medicaid program.

49. In return for receipt of federal subsidies, Tennessee is required to administer its Medicaid program in conformity with a state plan that satisfies the requirements of the Act and accompanying regulations. 42 U.S.C. §§ 1396–1396w; Tenn. Code Ann. § 71-5-102. In Tennessee, the Department of Finance & Administration administers the state Medicaid program through TennCare. Tenn. Code Ann. § 71-5-104. TennCare operates as a special demonstration project authorized by the Secretary of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315. The Department of Finance & Administration supervises

TennCare's administration of medical assistance for eligible recipients. Tenn. Code Ann. § 71-5-105-107. The Department of Finance & Administration is authorized to promulgate rules and regulations to carry out the purposes of TennCare. Tenn. Code Ann. §§ 71-5-124 to –134.

50. TennCare contracts with private managed care contractors ("MCCs") through contracts, known as Contractor Risk Agreements ("CRAs"), which must follow the requirements of 42 U.S.C. § 1395mm, along with any related federal rules and regulations. Tenn. Code Ann. § 71-5-128. The MCCs contract directly with providers to provide health care services to eligible TennCare beneficiaries. Providers who have entered into such a contract with an MCC are known as Participating Providers. Tenn. Comp. R. & Regs. § 1200-13-13-.01(89). Pursuant to the CRAs, TennCare distributes the combined state and federal Medicaid funding to the MCCs, which then pay Participating Providers for treatment of TennCare beneficiaries. TennCare-eligible persons seeking medical assistance enroll in an MCC to receive health care services from a Participating Provider.

4. CHAMPVA/Choice

51. Pursuant to 38 U.S.C. § 1701 *et seq*, the VA, through the VHA and CHAMPVA provides and pays for inpatient and outpatient health care services for veterans and their dependents and survivors.

52. Beginning in August 2014, Congress enacted the Veterans Access, Choice, and Accountability Act of 2014 ("VACAA") to enable eligible veterans to obtain medical care outside of the VA medical system from providers in their communities. Through VACAA, veterans may enroll in the Veterans Choice Program ("Choice"), which provides primary care, inpatient and outpatient specialty care, and mental health care for eligible veterans when the local VA health

care facility cannot provide the services for certain specified reasons, such as lack of available specialists, long wait times, or extraordinary distance from the veteran's home.

53. Congress also required the VA to develop a plan to consolidate all non-VA community care programs under Choice; the plan was required to address a number of elements, including "the structuring of the billing and reimbursement process, including the use of third-party medical claims adjudicators or technology that supports automatic adjudication." Choice claims are processed on behalf of VA by third-party administrators ("TPAs"), which include TriWest Healthcare Alliance ("TriWest"). The services provided by the TPAs are governed by contracts between each TPA and the VA (the "TPA contracts") and include building provider networks, scheduling appointments, collecting medical documentation, and making payments for medical care.

5. Requirements for Payment

54. For a health care provider to seek reimbursement from any of the Federal Health Care Programs, the provider must obtain a National Provider Identifier ("NPI") from CMS. The provider also must submit an enrollment application.

55. To be eligible to bill and receive reimbursement for medical services provided to TennCare enrollees, a participating provider must possess a unique provider identification number. All claims for reimbursement must be submitted under a valid provider identification number for the identified provider. 42 C.F.R. § 455.440.

56. For CHAMPVA/Choice, verification of eligibility in the form of an authorization from the TPA is required for reimbursement of costs associated with care provided to a veteran.

57. Once the provider is enrolled or credentialed, the provider may submit bills to the Federal Health Care Programs and TennCare for services rendered to the patients. The TPA

contracts require the providers of medical treatment to send their invoices to the TPAs, which must pay the providers and then bill the VA for these medical services.

58. A participating provider must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 431.107(b)(1).

59. The term "medical assistance," defined at 42 U.S.C. § 1396d and Tenn. Code Ann. § 71-5-103(7), includes payment for the cost of provision of medical services or procedures by qualified, licensed practitioners to an eligible person.

60. Medicare only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers also must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

61. TRICARE does not pay for services that are not authorized by law or that are fraudulently billed. 32 C.F.R. § 199.7(i)(3).

62. TennCare will only pay for medical items and services that are within the scope of the TennCare program and that are medically necessary. Tenn. Code Ann. § 71-5-144(a).

63. CHAMPVA and Choice only pay for covered services and supplies that are "medically determined to be reasonable and necessary." 38 C.F.R. § 17.30(a)(1). The contract between CPS and TriWest states: "TriWest may deny payment for services or supplies deemed to be not Medically Necessary."

64. To obtain reimbursement from the Federal Health Care Programs, providers submit a claim form, which typically is done electronically.

65. For claims to Medicare and TRICARE, providers submit CMS Form 1500 and/or its electronic equivalent, known as the 837P form, which contains the following certifications:

> In submitting this claims for payment from federal funds, I certify that: 1) the information on this form is true, accurate, and complete; 2) I have familiarized

> myself with all applicable laws, regulations and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were incident to my professional service by my employee under my direct supervision, except as otherwise permitted by Medicare or TRICARE … .
> NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

66. To obtain TRICARE reimbursement for services from physicians or other authorized individual providers, as with Medicare, the providers must submit a claim form to TRICARE that lists the procedure code or narrative description for each procedure or service for each date of service. 32 C.F.R. § 199.7(b)(2)(ix)(B). TRICARE claim forms also must bear a signature of the participating provider certifying that the medical care billed for was actually rendered to the beneficiary. 32 C.F.R. § 199.7(c). This signature certifies that the specific medical care listed on the claim form was actually rendered to the specific beneficiary at the level indicated on the claim form. *Id*.

67. To be reimbursed for medical services provided to TennCare enrollees, a participating provider must submit claims to TennCare using a standardized process that includes standard claims forms and standardized coding. Tenn. Code Ann. § 71-5-191. Participating providers submit claims for reimbursement for services and procedures to MCCs through either paper or electronic forms. On these forms, the participating provider identifies the services and procedures for which reimbursement is sought using standard, uniform code numbers, including CPT codes.

68. For Medicaid payments, providers also certify on Form CMS 1500 that "services were medically indicated and necessary to the health of this patient." It also contains another "NOTICE" that "the foregoing information is true, accurate and complete … and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

69. The Medicare Part B Electronic Data Interchange ("EDI") enrollment documentation, which is signed and submitted when a provider enrolls for electronic billing with a MAC, also contains an acknowledgement "that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See, e.g., Cahaba Medicare Part B EDI Application* (09/2013 v2.51); *Interactive EDI Agreement for Palmetto; EDI Enrollment for Novitas Solutions*.

70. Among the information the provider includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Chapter 23, § 20.7 *et seq*. CMS assigns reimbursement amounts to CPT and HCPCS codes.

71. TRICARE utilizes and incorporates CPT codes to describe the scope of allowable services. TRICARE Policy Manual 6010.60-M, Ch. 1, § 1.1, ¶ 3.4.1.2.

72. TriWest's contract with participating providers also states that it may utilize the standard industry code review system in adjudicating claims and determining appropriate levels of coding.

73. Providing accurate CPT and HCPCS codes on claims submission forms is material to and a condition of payment for the Federal Health Care Programs. *See, e.g.*, Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

74. The Federal Health Care Programs and TennCare routinely deny payment to providers who bill for codes when the criteria for those codes is not actually met, including when the services are not medically necessary.

V. CPS IS FORMED AND BECOMES A VEHICLE FOR FRAUD

75. CPS was originally formed as Skyline Anesthesia Services, PLLC on July 11, 2000. The company's name was changed to Anesthesia Services Associates, PLLC on June 26, 2001. At that time, the company primarily provided anesthesia services, was member-managed and operated out of offices in Hendersonville, Tennessee. Dickerson was a founding member and President of the company at the outset.

76. Carrero joined the company in or about June 1, 2004 and was first listed as a member in the Annual Report dated March 23, 2006.

77. As the company began focusing on pain management, Anesthesia Services Associates, PLLC assumed the name of, and started doing business as, CPS, per an application signed by Dickerson, which is dated June 30, 2006.

78. One of the founding physicians of CPS, Dr. Timothy Arney, was the catalyst in building the pain management practice, which began to expand rapidly when Kroll joined CPS in

August of 2006. At that time, Sarah Trent, who had worked with Kroll, came on board with CPS and was the only nurse practitioner CPS had on staff.

79. Kroll is first listed as a member in CPS's Annual Report dated March 21, 2007.

80. In 2011, as the company grew, Kroll suggested that Davis, whom he had known through Davis's role as a medical device sales representative for Medtronic PLC, would be a good choice to run the day-to-day business affairs of CPS.

81. Davis was hired as the CEO of CPS on or about June 2, 2011, through an employment agreement, which was dated May 20, 2011. At that time, his salary was $70,000.00, with an annual bonus of 25 percent of the first $2 million of CPS's net profits and 4 percent of net profits thereafter.

82. Once Davis became CEO, CPS rapidly grew into a moneymaking enterprise, with at one-time over 60 locations, including clinics in Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Ohio and South Carolina, in addition to Tennessee. During 2012, CPS added nine additional locations and began operating its own testing facility in Franklin, Tennessee, which was fully functional in or about July 2012. In 2013, 20 additional locations were added in East and West Tennessee, and in 2014, over 30 locations opened across the other states.

83. CPS also began operating a pharmacy as part of its business, for which it utilized the name of Comprehensive Wellness Pharmacy, pursuant to an application dated September 30, 2013. The Clarksville, Tennessee based pharmacy began operating in August 2014. The pharmacy focused largely on compounded creams for pain and scar relief, as well as oral and transdermal medications for CPS's pain management patients. However, the pharmacy had limited ability to process Medicare claims.

84. Muench became a member of CPS on or about March 4, 2014.

85. Dr. Arney passed away on August 14, 2014. On that same date, CPS amended its Articles of Incorporation to be director-managed, as opposed to member-managed.

86. From August 14, 2014 to present, Kroll, Dickerson and Muench were on the Board of Directors for CPS.

87. Upon information and belief, in or about 2015, the Owners caused CPS to borrow $1.5 million to open a larger testing facility in Brentwood, Tennessee that focused on UDS, pharmacogenetic testing, and hormone panels, among other testing.

88. At the February 11, 2016 meeting of the Board of Directors, Kroll was approved as Chief Medical Officer.

89. While CPS implemented policies that were intended to be uniform as CPS added each new location, the same was not true for the terms of the compensation arrangements with each office acquisition or physician hired. Davis typically negotiated or approved the terms for CPS's new locations and physicians, although some were approved by Dickerson.

90. CPS recruited new physicians and groups based on a promise of enhanced revenue from the self-referrals, particularly for UDS. Typically, physicians received between fifty and sixty percent of their net revenues, with an additional bonus portion based on contributions into a pool that consisted of revenues from the physicians, as well as the mid-levels they supervised, for self-referrals for UDS, genetic and other blood testing, DME, iPad tests and other DHS.

91. As part of his efforts to expand CPS's reach into East Tennessee, Davis negotiated a sweetheart deal with Smith. Pursuant to an Asset Purchase Agreement, dated May 23, 2013, between CPS and Smith, CPS acquired the Cleveland, Tennessee clinic that Smith, a chiropractor, had previously operated. Smith also had a separate Employment Agreement with CPS, also dated

May 23, 2013, through which he stayed on as a manager and was entitled to 94 percent of the revenue collected, as well as 75 percent of all revenue collected for ancillary services. The term of this agreement ran for ten years and eventually covered two other clinic locations. As discussed in more detail below, because of his extraordinary compensation package, Smith was incentivized to ensure that the providers he managed ordered as much testing and ancillary services as possible.

92. The Owners themselves were compensated with 100 percent of their net revenues collected, plus a percentage from the pool of ancillary services revenues to which CPS providers contributed. Upon information and belief, Davis calculated the Owners' distributions and did not provide transparency as to his calculations.[2]

VI. DEFENDANTS' FRAUD ON THE GOVERNMENT HEALTH CARE PROGRAMS

93. The Owners and Davis viewed every CPS patient as an opportunity to make money, without regard to the individualized need for treatment.

94. Virtually from the outset of his employment with CPS, in an August 19, 2011 email to Kroll, Dickerson, Carrero and Arney, Davis articulated his business model for CPS, explaining that the "actual monetary value of a new patient FAR outweighs that of a procedure." He made it clear that a new patient visit could be a self-referral, which included UDS, DME, a Level 4 office visit, and an electromyogram ("EMG") that would generate $2,400.

95. Following up on Davis's stated objectives, CPS found ways to bill the Federal Health Care Programs and TennCare a multitude of claims for every patient. Specifically, CPS ensured that its providers ordered at least six urine tests on every patient, pharmacogenetic blood tests, Health and Wellness panels, iPad tests purportedly to measure depression and suicidal

[2] Upon information and belief, in addition to the Owners, CPS has certain minority owners that do not have any input into the operations of the company and received minimal compensation throughout the relevant time period.

thoughts, and ancillary services wherever possible. CPS then created a bonus policy that incentivized its providers to ensure that these tests and services were being ordered, even if there was no medical necessity. Notably, bonuses only were paid for testing and ancillary services ordered through CPS.

96. If an opportunity for income was missed, Davis personally would alter the claims to change the coding to obtain the maximum amount of reimbursement.[3]

A. CPS Develops Unlawful Policies For Patient Testing

97. The most profit-enhancing way in which CPS defrauded the Federal Health Care Programs and TennCare was through billing for non-reimbursable and/or medically unnecessary testing that CPS performed on its patients, including urine drug testing, which was accompanied by specimen validity testing, blood testing for genetic risk factors, and psychological testing using iPads.

1. Urine Drug Testing

98. Although testing urine for drugs may be an appropriate means to analyze and monitor the treatment of pain patients, as set forth below, Defendants used this tool as a means to bilk the United States and Tennessee out of millions of dollars.

a. General Guidelines on UDS

99. Typically, providers utilize drug tests to verify whether pain patients are compliant with taking their prescription drugs and to confirm that the patient is not taking other drugs, including illicit ones, which could interfere with their treatment or pose risks of overdose. For this

[3] An audit trail revealed that between 2012 and 2014, Davis accessed approximately 7,500 claims. Upon information and belief, Davis – who is not a provider and did not treat any CPS patient – entered these locked fields and changed the coding from what the provider noted to other codes that yielded a larger reimbursement amount from the Federal Health Care Programs.

reason, providers often perform drug tests on pain patients at appropriate intervals when medically necessary to manage the patient's care. When urine testing is medically necessary, the Federal Health Care Programs and TennCare will provide reimbursement for such tests.

100. Common practice in the medical community is to first order a qualitative test of urine to detect the presence or absence of drugs or metabolites (often known as "analytes") in the sample. A typical qualitative drug test panel may include testing for the presence of cocaine, opiates, opioids, heroin, amphetamines, methamphetamine, benzodiazepines, phencyclidine (PCP), MDMA, barbiturates, methadone, tricyclic antidepressants, synthetic or designer drugs, oxycodone, and THC. Qualitative testing does not measure the concentration of drugs in the sample.

101. For patients deemed at high risk for the potential to abuse drugs, or if the provider has a concern about the drugs already in the patient's system, the medical community recommends on site Point-of-Care ("POC") testing to obtain immediate results of the qualitative testing. POC testing is reimbursed at a lower rate than testing performed off-site.

102. Depending on the initial results from the qualitative testing, it may, in some instances, be medically appropriate to next perform a quantitative drug test to determine the concentration of specific drugs in a patient's system. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the specific drug(s) present. Unlike the qualitative test, which can test for all drugs in the sample at once, quantitative testing requires that a separate test be performed for each different drug. Because each drug tested for requires a separate test, the testing equipment needed is much more sophisticated than what is needed at the qualitative level. Thus, quantitative testing is more expensive to perform and reimbursed at a higher rate than qualitative testing.

103. Medicare rules limit quantitative screening, in most cases, to clinical situations where qualitative screening has been performed and the results of that test indicate that quantitative tests for particular drugs are needed. The frequency of qualitative drug testing also must be individualized to patient need in order to be reasonable and medically necessary. Ongoing testing in chronic opioid therapy patients can be acceptable, as can randomized testing, but only under specific conditions particular to the individual patient.

104. For this reason, the Federal Health Care Programs and TennCare generally require providers to make testing decisions on a case-by-case basis, as most patients will not test positive for any drugs on a screening test (save those being prescribed to them), or if there are positive results, those are typically limited to no more than a few drugs.

105. Many of the MACs also require providers to assess patient risk on an individualized basis to determine the appropriate frequency of testing, as well as which urine drug tests should be performed.

106. For these reasons, most patients do not warrant quantitative urine drug testing. Even in those cases where quantitative testing is appropriate, it is rarely medically necessary to perform such testing for each of the drugs that the quantitative test detects.

107. On or about October 1, 2015, Cahaba issued LCD L34501, entitled "Pathology and Laboratory: Qualitative Drug Testing," which states qualitative testing "may be followed by confirmation with a second method, only if there is a positive or negative finding inconsistent with the setting of a symptomatic patient." In other words, the results must be received and analyzed prior to the provider ordering the quantitative testing. Cahaba further indicated: "Routine 'per visit' drug testing in chronic pain patients is noncovered." Thus, providers may not use a standing order that authorizes the same set of tests for each patient.

108. As of June 15, 2015, Cahaba provided notice to providers that effective October 1, 2015, LCD L35920, entitled "Pathology and Laboratory: Quantitative Drug Testing," would go into effect. This LCD expressly stated: "[P]hysician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record. Some labs offer comprehensive definitive drug testing panel ("CDDP") of 40 or more drugs. It is not reasonable and necessary to bill individual billing codes for this comprehensive testing."

109. Cahaba further indicated: "Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record."

110. Non-covered services were defined in part as: "Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine."

111. Palmetto's LCD 35724, which was effective October 1, 2015, did not allow for any standing orders with respect to UDS, and instead required providers to engage in a patient-specific risk analysis to determine how often UDS should be performed on patients. For low risk patients, random testing should occur "1-2 times every 12 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage." For moderate risk patients, random testing should occur one to two times every six months. For high risk patients, random testing should be performed one to three times every three months. Palmetto

also did not reimburse for specimen "validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine."

112. The prior relevant LCD for Palmetto, LCD 35105, which was effective December 15, 2014, contained similar language.

113. NGS also had an LCD for Qualitative Drug Screening (L28145), which was effective July 18, 2008 through September 30, 2015, which allowed for testing "when the result of the drug screen is different than that suggested by the patient's medical history, clinical presentation or patient's own statement."

114. From 2011 to 2015, qualitative testing was billed under codes G0431 and G0434.

115. In 2016, codes G0431 and G0434 were discontinued and replaced with G0477, G0478, and G0479 for presumptive testing. In 2017, these codes were replaced with CPT codes 80305, 80306 and 80307.

116. CDDP Panels and quantitative testing generally were billed under CPT code 84311 throughout the relevant time period.

117. Beginning in 2015, CPT code 80299 was used for quantitative testing for therapeutic drugs without a specific CPT code assigned. In 2016, CMS implemented HCPCS codes G0480, G0481, G0482 and G0483 for definitive or quantitative drug testing.

118. With respect to specimen validity testing, which "is used to analyze a urine specimen to ensure that it is consistent with normal human urine and has not been adulterated or tampered with," HHS-OIG has indicated that "when used for the purpose of determining whether a specimen is adulterated, the test results are not being used to manage a beneficiary's specific medical problem. In these cases, specimen validity testing is not a separately billable Medicare-

covered service." *Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests*, HHS-OIG Pub. A-09-16-02034, February 2018.

119. Indeed, as far back as 2010, some of the MACs issued LCDs that indicated specimen validity testing was not covered.

120. During the relevant time period, claims for specimen validity testing were submitted under CPT codes 82565, 82570, 82670, 83986, 84075 and 84295, among others.

b. CPS's UDS Policies Were Unlawful

121. Beginning in September 2011, shortly after Davis joined CPS, the Owners increased the amount of urine drug testing being performed on their patients as an easy way to obtain money from the Federal Health Care Programs and TennCare.

122. Specifically, in a September 8, 2011, email from John Davis to PhyData, CPS's third party billing company at that time, Davis instructed PhyData to "bill as 12 units every time" for urine drugs screens on the patients of Arney, Dickerson, Carrero, Kroll and Muench. The Owners were aware of this routine and medically unnecessary testing and were copied on this email, which was referenced as "VERY URGENT: UDS 80101." Davis further noted that the failure to bill the full amount were "errors" that were "very costly for CPS." [Effective April 1, 2010, CPT code 80101 was replaced with HCPCS code G0431 for qualitative testing.]

123. Not only did CPS implement a system whereby it would order excessive amounts of urine drug testing on virtually every patient, it also ensured that it would capture even more revenue relating to such testing costs by opening up its own testing facility.

124. In or about July 2012, CPS began operating a testing facility in Franklin, Tennessee, which was fully operational by year-end 2012.

125. As of at least October 2013, CPS required its providers to send patient urine samples for qualitative testing at its lab under HCPCS code G0431, which carried a reimbursement rate of $100, instead of the $19.84 that CPS would have been paid if testing was done on-site.

126. CPS developed Urine Drug Screening Guidelines, dated March 5, 2014. The policy provided for all new patients to be tested, and any patient receiving narcotics would be tested approximately six times per year and, if there was a red flag or suspicious behavior, testing would be done more frequently. There was "NO in clinic testing of urine samples" or POC testing performed at CPS, as it was "not conducive to [CPS's] current clinic model."

127. Renata McGhee, the Director of Policy/Procedure & Clinical Compliance for CPS, distributed these guidelines, which Kroll pre-approved, to CPS providers on March 11, 2014.

128. As of July 2014, CPS continued to test the urine of all new patients, and any patients receiving narcotics were tested six times per year and more often if there was a red flag. There was no in-clinic testing performed.

129. CPS had weekly conference calls with providers to ensure that they were ordering and billing for the full panel of UDS, which included specimen validity testing.

130. As CPS expanded, in September 2014, it wanted to ensure that all providers were capturing the maximum amount of revenue on UDS. For this reason, CPS adopted a policy that required providers to use a standing order that authorized a battery of tests to be performed by CPS's lab.

131. On October 2, 2014, Pam Arnold, the Director of Compliance Integrity for CPS, emailed Sarah Trent, then Director of Clinician Education for CPS, with a copy to Jeff Hurst, the Chief Operations Officer for CPS, regarding the UDS standing order. She noted that it only allowed providers to mark "Non-Medicare" or "Medicare" and then "the provider was 'supposed'

to document in their notes which drugs are included in the analysis." Ms. Arnold stated: "Many of our providers do not document this." She then asked: "If we put in place the standing order, does that alleviate the need for providers to include this in their documentation?" Ms. Trent replied: "It should because we will have defined what each one is as a standing order in writing that we can provide…"

132. In or about October 8, 2014, at Davis's direction and with Kroll's approval, CPS emailed providers that they were required to sign a form for a standing order on UDS that would be done at CPS's off-site lab in Franklin, Tennessee.

133. Moreover, each of the Owners received a copy and was fully aware of the standing order protocol. Upon information and belief, the Owners abided by the standing order protocol and CPS's UDS policies, which is reflected in the claims submitted to the Federal Health Care Programs and TennCare.

134. Kroll and Dickerson executed the standing order.

135. Following up on this, the training manual for CPS's electronic medical record system, eClinicalWorks ("eCW"), which was made available to CPS personnel in or about April 17, 2015, contained a template for "Ordering Urine Drug Screens (UDS)" which required providers to order both qualitative and quantitative drug screens. CPS further required providers to order UDS for established patients at minimum every two months, regardless of whether there was an individualized need for their medical management. Often patients were drug tested on every visit, which could be monthly.

136. CPS providers ordered UDS by selecting one of several types of drug testing panel options in CPS's eCW system. As Ms. Arnold had indicated, the panels were differentiated by Medicare or non-Medicare and "Long Term Use" or "Medication Monitoring."

137. Once the selection for the drug screen was made, CPS providers would send the urine to CPS's lab for both qualitative and quantitative urine drug testing, as well as specimen validity testing. Notably, quantitative testing was ordered from the outset, even before results from the qualitative tests had been obtained. Thus, even if the drug screen was negative, CPS performed the quantitative drug screen without any medical necessity.

138. The results of the drug testing often would not be available in eCW until seven to ten days after the lab received the specimen. This did not deter CPS providers from prescribing pain medication, including opioids, without having the test results.

139. Moreover, despite the excessive amounts of drug testing being performed, CPS providers often did not review the results in considering whether to prescribe opioids on follow up visits. For example, CPS providers often failed to consider whether a patient who tested negative for opioids, but was presently being treated with those drugs should continue to receive a prescription. The relevant question for these patients should have been whether they filled the prescription, and if so, why it was not present in their system (*i.e.*, did they sell it or gave it to someone else).

140. Indeed, it is important for providers to have real time results of drug testing when determining whether to prescribe opioids. Nevertheless, the policy at CPS, which was approved by Kroll, prohibited POC or in-clinic testing. CPS locations did not even possess the equipment necessary to perform POC testing, even if that was determined to be medically necessary by a provider who was treating a patient in real time. Instead, there were pre-addressed shipping labels so that the specimens could be mailed off to the CPS lab, where it would take over a week to obtain the results.

141. It is estimated that each provider was sending approximately twenty specimens for testing each billing day, and the Franklin lab was performing upwards of 600 tests per day.

142. As CPS grew its practice, there was a noticeable increase in claims related to urine drug and the related specimen validity testing.

143. For example, when Dr. Thomas Brummett and Dr. Wynndel Buenger joined CPS in 2014, their UDS claims went from approximately one percent of their total Medicare payments to over forty percent.

144. In sum, CPS should not have utilized a standing order for urine drug testing. As discussed above, a standing order is itself improper, as it does not allow for any determination of patient-specific risk or medical necessity for each patient.

145. CPS's policy of testing virtually all new patients with the same set of qualitative drug tests, specimen testing and then automatic quantitative testing without regard to the qualitative testing results did not comply with the requirements of the various MACs and lacked medical necessity, including by duplicative drug testing.

146. Similarly, for follow up patient visits, CPS again employed a standing order to test patients for a panoply of drugs, regardless of individual patient history, and again with specimen validity and automatic quantitative testing performed regardless of the qualitative testing results.

147. Further, as part of the panel of tests, CPS providers also improperly bundled tests such that there was an overlap in the types of drugs for which the urine was being tested. CPS would routinely subject each specimen to at least 16 different types of tests, including specimen validity testing. Some patients had as many as 51 tests performed on their urine. Duplicative testing is not reimbursable by the Federal Health Care Programs or TennCare.

148. CPS lacked any medical necessity to perform the majority of these tests and did not have the requisite medical documentation to support the testing.

149. CPS providers often ignored or overlooked the testing results in making decisions on whether to prescribe opioids on follow up visits.

150. CPS also lacked any medical necessity for employing a standing order as to the frequency of the testing on specific patients.

c. Investigations Into, and CPS's Overuse of, UDS

151. The sheer number of urine drug tests, with its accompanying specimen validity testing, for which CPS sought reimbursement from Medicare raised red flags for CMS.

152. On July 14, 2014, AdvanceMed, a Zone Program Integrity Contractor ("ZPIC") for CMS, performed an audit covering claims from January 1, 2012 to May 31, 2014.

153. CPS received a request for records from the ZPIC on July 17, 2014.

154. Thus, when CPS circulated its formal standing order in October of 2014, it was already on the radar for its overutilization of UDS.

155. On March 17, 2015, the ZPIC notified CPS that the audit results indicated a 96% error rate based on the wrong date of service and no medical necessity for 189 claims, which extrapolated to a $27,428,800.00 over-payment by Medicare.

156. CPS appealed this determination to Cahaba, which largely upheld the ZPIC's findings in a June 23, 2015 Redetermination Notice, a corrected version of which was dated July 6, 2015 that included the dates of service at issue. In that Redetermination Notice, Cahaba found that 177 of the 189 claims lacked medical necessity, and recalculated the overpayment as $27,399,549.71.

157. CPS submitted a Request for Reconsideration to C2C Solutions, the Qualified Independent Contractor ("QIC"), on August 19, 2015.

158. As CPS's UDS policies were coming under scrutiny, its compliance personnel were working to implement new guidelines that purportedly would take into account patient risk. CPS's Compliance Department issued revised Urine Drug Screening Guidelines, effective September 1, 2015, which were approved by Kroll. These guidelines noted that it was "not appropriate to order a urine drug screen on every patient at every visit" and instead "risk stratification must be demonstrated in order to meet medical necessity." CPS then purported to create three risk panels: low, medium and high. POC testing, however, still was not allowed.

159. On September 18, 2015, the Compliance Committee, which included Davis and Kroll, approved another revision to the UDS Guidelines, which would be effective on November 1, 2015.

160. On October 20, 2015, the QIC issued a decision upholding the ZPIC's findings.

161. In response to the ZPIC audit, CPS compliance personnel also conducted an internal review of the claims and providers at issue. CPS's compliance personnel noted that the claims related primarily to UDS issues at the East Tennessee clinics, and in particular the Cleveland location, which Smith oversaw.

162. Once CPS compliance personnel began reviewing the medical records of some of the providers in Cleveland, they quickly saw a pattern where almost every patient had the same set of tests performed based on whether they were male or female, regardless of the basis for the visit and certainly without regard to medical necessity.

163. In an attempt to curtail the submission of false claims, on November 3, 2015, members of CPS's internal Compliance Committee, which included Sarah Trent, provided training

on UDS to providers in the East Tennessee clinics who had been ordering UDS on every patient on every visit.

164. On December 9, 2015, the CPS Education & Compliance Team revised its standing order policy and instructed providers that "the number of two-month cycle appointments should be limited to very specific and well documented reasons."

165. On March 1, 2016, Pam Arnold, CPS's Executive Director of Organizational Development & Risk Management, issued further guidance that urine drug testing should be based on risk factors, and that two panels would be available for testing, which consisted of a Complete Panel for all drugs and a Low Risk panel. In this email, she also noted that tests could still be ordered a la carte for many drug classes.

166. CPS then issued revised Urine Drug Screening Guidelines, effective March 15, 2016, which were approved by Kroll. These Guidelines again purported to provide for risk stratification testing for patients receiving narcotics. Screening should be done one to two times per year for low risk patients, and four to six times per year for high risk. CPS recommended that a Complete Panel should be used for new patients, patients who are being considered for opioids, random drug screen and high risk. Thus, even low risk patients would receive a full set of UDS at least once a year.

167. On March 16, 2016, at a meeting of the Clinical QA Committee, which Kroll attended, it was noted that patients should be tested four times a year as a standard, and high risk patients should be tested six times a year and more often as needed.

168. On March 18, 2016, Sarah Trent emailed providers about the implementation of the new UDS panel process, which would begin on March 21.

169. At the June 24, 2016 Compliance Committee meeting, it was noted that Kroll would need to approve protocol for UDS collection and other matters.

170. Despite the training that the compliance personnel had provided in East Tennessee, there was little improvement. The Compliance Committee eventually voted to have each of the providers train specifically with Kroll.

171. Specifically, one of these providers, Anita Bayles, a nurse practitioner, failed to change her practices of over-ordering UDS, having a schedule that indicated more patients were seen than was appropriate, and over-prescribing of opioids. Compliance personnel also raised questions concerning patient harm and the potential liability to CPS as a result of her conduct.

172. On September 15, 2016, CPS's Compliance Committee, which included Kroll, voted unanimously to terminate Anita Bayles.

173. Nevertheless, after a conference call involving members of the Compliance Committee, Davis, and Dr. Niendorff, who was the supervising physician for Ms. Bayles, Davis ultimately made the decision to keep Ms. Bayles on staff because of her ability generate revenues.

174. Kroll was aware of this decision, yet failed to take any action.

175. It is unclear whether the other Owners were aware of this situation, but they certainly were aware of the ZPIC audit and should have known about the Compliance Committee review.

176. In the meantime, CPS continued to exert extraordinary efforts to overturn the findings of the ZPIC. After a lengthy appeal process, CPS worked with the QIC to reopen the decision, and on August 16, 2016, CPS provided additional documentation that it purported to demonstrate the correct dates of service and letters of medical necessity, all signed by Kroll.

177. On September 1, 2016, the QIC issued another Reconsideration Decision reversing most of the denials, which appears to be based solely on the date of service, as it did not address whether there was any medical necessity for the UDS that was a part of the original overpayment determination.

178. However, because of the excessive billing, on or about October 16 and 20, 2016, Cahaba notified CPS that seven East Tennessee providers (Anita Bayles, Christine Ladd, Dana Simpson, Jennifer Rose, Laura Godwin, Samantha Bryant and Tina Johnson) were placed on prepayment review, largely for their overutilization of UDS, which meant that claims submitted for these providers would not be processed until after the documentation confirmed that the services were medically necessary and properly reimbursable.[4]

179. CPS again issued another set of Urine Drug Screening Guidelines, effective November 7, 2016, which were approved by Kroll and signed by Davis. However, there was no mention of risk stratification in this set of guidelines, and instead testing for patients receiving narcotics was recommended at least six times per year, and more if there were red flags.

180. Despite the issues raised by the audit, internal practices regarding standing orders for UDS at CPS remained largely unchanged throughout this time period. As of February 26, 2017, Kroll was still in favor of standing orders that did not emphasize individual patient risk.

181. In the March 24, 2017 update to the Urine Drug Screening Guidelines, CPS published a suggested table of frequency of testing based on low, moderate and high risk groups. New patients being considered for opioid therapy should be tested, and testing must be based on

[4] Because of an oversight, these providers no longer were placed on prepay status when Palmetto took over for Cahaba in February of 2018.

documented medical necessity and reviewed by the provider for the risk group determination. POC testing still was not performed.

182. On April 30, 2017, Erin Galloway, the Director of Provider Education for CPS, emailed CPS providers that effective May 1, 2017, they would have the option of choosing a complete panel or a limited one, which did not test for illicit substances. Providers continued to have the option of ordering additional testing a la carte, provided that there was medical necessity.

183. Ultimately, it was not the ZPIC audit or the government investigation that impacted CPS's unlawful UDS practices. Rather, it was the February 2018 change from Cahaba to Palmetto, which had more stringent requirements for reimbursement of UDS, that dried up the well of "liquid gold" that had kept CPS in business.

184. In preparation for the change, per a February 22, 2018 email, CPS notified all providers that "all drug screen orders be placed AFTER the patient has been seen by the provider," which required providers to assess patients individually.

185. Per a March 16, 2018 email, it was finally clear that CPS providers no longer could use a "panel" to order UDS.

186. Nevertheless, in April 2018, Kroll was still pushing UDS, even on patients who were receiving injections and not medication.

187. Upon information and belief, virtually all CPS locations continued the practice of using a standing order that incorporated bundles of drug tests, including specimen validity testing and automatic quantitative testing without regard to patient risk factors from 2014 until Palmetto became the MAC for Tennessee on February 26, 2018. CPS continued to order at least some medically unnecessary UDS until it ceased operations.

188. For this reason, it is not surprising that Palmetto's Railroad Retirement Board division also conducted an investigation into CPS's UDS practices, and specifically the claims submitted with Kroll as the Rendering Provider. Palmetto flagged Kroll as an outlier for his claims from January 1 to December 31, 2016 with HCPCS and/or CPT codes G0477-0479, 80305-80307 and G0480-0483. Palmetto sent Kroll a letter advising him of his billing pattern. Six months later, follow up analysis was performed, and he remained an outlier. As a result, Palmetto initiated a post-pay review of his services.

189. A subsequent investigation found overpayments relating to Kroll's UDS for RRB patients from May 12, 2017 to April 30, 2019 in the amount of $12,181.31.

d. Defendants' Extraordinary Profits from Unlawful UDS

190. The amount that CPS billed and was reimbursed by the Federal Health Care Programs and TennCare for UDS is staggering. For this reason, CPS considered UDS to be "liquid gold" – with revenues of tens of millions of dollars for what was largely unnecessary medical testing, as set forth in detail below.

191. CPS providers who sought reimbursement from the Federal Health Care Programs and TennCare relating to UDS utilized over forty different CPT and HCPCs codes, including but not limited to the following:

CODE	DESCRIPTION
80101	Drug screen
80154	Benzodiazepines level
80299	Quantitation of therapeutic drug
80307	Testing for presence of drug
81003	Automated urinalysis test

82055	Alcohol (ethanol) level
82145	Amphetamine or methamphetamine level
82205	Barbiturates level
82520	Cocaine (drug) level
82541	Chemical analysis using chromatography technique
82542	Chemical analysis using chromatography technique
82565	Blood creatinine level
82570	Creatinine level to test for kidney function or muscle injury
82646	Dihydrocodeinone (drug) measurement
82649	Dihydromorphinone (drug) level
82670	Estradiol (hormone) level
83788	Mass spectrometry (laboratory testing method)
83789	Mass spectrometry (laboratory testing method)
83805	Meprobamate (sedative) level
83840	Methadone level
83925	Opiates (drug) measurement
83986	Body fluid pH level
83992	PCP drug level
84075	Phosphatase (enzyme) level
84295	Blood sodium level
84311	Chemical analysis using spectrophotometry (light)
G0396	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes
G0397	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes

G043l	Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter
G0434	Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, tof, maldi, ldtd, desi, dart, ghpc, gc mass spectrometry), includes sample validation when performed, per date of service
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to gc/ms (any type, single or tandem) and lc/ms (any type, single or tandem and excluding immunoassays (e.g., ia, eia, elisa, emit, fpia) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to gc/ms (any type, single or tandem) and lc/ms (any type, single or tandem and excluding immunoassays (e.g., ia, eia, elisa, emit, fpia) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
G0482	Definitive drug test, identification of 15-21 drug classes
G0483	Definitive drug test, identification of 22 drug classes
G6031	Benzodiazepines
G6042	Amphetamine or methamphetamine
G6044	Cocaine or metabolite
G6045	Dihydrocodeinone
G6046	Dihydromorphinone
G6052	Meprobamate
G6053	Methadone
G6056	Opiate(s), drug and metabolites, each procedure
G6058	Drug confirmation, each procedure

192. At various times, CPS utilized these codes when submitting claims to the Federal Health Care Programs and TennCare for testing that was *per se* not covered or otherwise medically unnecessary.

193. Had the Federal Health Care Programs and TennCare known that the testing was done solely for the purposes of specimen validity testing, not medically necessary or otherwise lacked the requisite medical documentation, they would have denied payment for these claims.

194. From 2011 to 2018, the Federal Health Care Programs paid CPS over $70 million for UDS claims, and TennCare paid CPS over $9 million.

195. From 2016 to 2018, over $10 million was paid by Medicare based on claims submitted just for code G0483, which was for quantitative testing.

196. The Federal Health Care Programs paid almost $2 million for claims submitted relating to UDS with Kroll listed as the Rendering Provider; over $300,000 for claims relating to UDS with Carrero listed as the Rendering Provider; and over $250,000 for claims relating to UDS with Dickerson listed as the Rendering Provider.

197. Because the Owners and Davis directly profited from CPS's overall revenues collected, which came largely from the UDS billing, they directly profited from not only their use of UDS, but CPS's company-wide policy.

198. Smith also profited from the excessive UDS and specimen validity testing in the clinics he managed.

i. <u>Non-Reimbursable Specimen Validity Testing</u>

199. While much of the submission of false claims relates to lack of medical necessity, there are certain codes for specimen validity testing for which CPS routinely billed the Federal Health Care Programs and TennCare that are non-reimbursable. Specifically, CPS performed

specimen validity testing, such as for creatinine, oxidants, hormones specific gravity and pH, even though such testing is not reimbursable.

200. For example, CPS tested patients for code 82570, which was related to the creatinine level as a way to determine if there was kidney failure, and 83986, which was for pH levels. In 2016, CPS substantially halted its practice of billing for CPT codes 82570 and 83986. Instead, CPS providers began submitting a large number of claims under CPT code 82670, which measures the amount of hormones in a patient's body.

201. Some CPS providers also submitted claims for CPT code 84295, which tests the level of sodium, and CPT code 84075, which tests for the presence of phosphatase enzymes to determine if there is an issue with the liver, gallbladder or bones.

202. The claims submitted to and paid by the Federal Health Care Programs and TennCare for CPT codes 82565, 82570, 82670, 83986, 84075 and 84295 that were performed solely for the purpose of specimen validity testing are not reimbursable by the Federal Health Care Programs or TennCare and lack medical necessity.

203. Had the Federal Health Care Programs and TennCare known that such specimen validity testing lacked the requisite medical documentation, was not medically necessary or otherwise did not satisfy the standards for reimbursement, they would not have paid CPS for these claims.

204. From 2011 through 2018 when CPS closed, Medicare paid CPS over $1 million for 124,070 claims and 209,395 claim lines for specimen validity testing submitted under CPT codes 82565, 82570, 82670, 83986, 84075 and 84295.

205. Of this amount, $82,865.24 is attributable to Kroll for 13,006 claims with 24,014 claim lines, $3,543.33 is attributable to Carrero for 362 claims with 714 claim lines, and $3,147.99 is attributable to Dickerson for 279 claims with 542 claim lines.

206. Some examples of the false claims that CPS and the Owners submitted relating to the specimen validity testing when urine drug testing also was done are as follows:

a. Carrero submitted a claim to Medicare for specimen validity testing on November 9, 2011 on patient S.B. under CPT codes 82570 (creatinine) and 83986 (pH), with a Modifier 59 code on each, for which Medicare paid CPS a total of $20.28.[5]

b. Carrero submitted a claim to Medicare for specimen validity testing on January 14, 2015 on patient J.M. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS $9.61.

c. Carrero submitted a claim to Medicare for specimen validity testing on March 8, 2017 on patient W.B. (a male) under CPT code 82670 (estradiol-hormone), for which Medicare paid CPS $37.55.

d. Dickerson submitted a claim to Medicare for specimen validity testing on December 1, 2011 on patient J.M. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $10.14.

[5] Modifier 59 is used to identify distinct or independent procedures or services, other than evaluation and management ("E&M") services, that are performed on the same day and not normally reported together. *Medicare Claims Processing Manual*, Ch. 23, § 20.9.1.1. This is considered an add-on code and was not properly billed for on these claims.

e. Dickerson submitted a claim to Medicare for specimen validity testing on December 1, 2011 on patient C.P. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $10.14.

f. Dickerson submitted a claim to Medicare for specimen validity testing on April 18, 2012 on patient B.A. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $10.21.

g. Dickerson submitted claim to Medicare for specimen validity testing on July 25, 2014 on patient T.C. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $11.70.

h. Less than two months later, Dickerson submitted a claim to Medicare for specimen validity testing on September 19, 2014 on the same patient T.C. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $11.70.

i. Dickerson submitted a claim to Medicare for specimen validity testing on June 14, 2016 on patient B.A. under CPT codes 82565 (creatinine), 84075 (phosphatase) and 84295 (sodium), for which Medicare paid CPS a total of $2.77.

j. Dickerson submitted a claim to Medicare for specimen validity testing on January 23, 2017 on patient T.M. under CPT codes 82565 (creatinine), 82670 (estradiol-hormone), 84075 (phosphatase) and 84295 (sodium), for which Medicare paid CPS a total of $40.34.

k. Kroll submitted a claim to Medicare for specimen validity testing on November 16, 2011 on patient D.M. under CPT codes 82570 (creatinine) and 83986 (pH), for which Medicare paid CPS a total of $10.14.

l. Kroll submitted a claim to Medicare for specimen validity testing on January 24, 2018 on patient R.S. (a male) under CPT code 82670 (estradiol-hormone), for which Medicare paid CPS a total of $33.80. The address for patient R.S. is listed in North Carolina.

m. Kroll submitted a claim to Medicare for specimen validity testing on April 3, 2018 on patient P.B. under CPT codes 82565 (creatinine) and 84075 (phosphatase), for which Medicare paid CPS a total of $12.46.

ii. Other Examples of Medically Unnecessary UDS

207. In addition to the improper billing for specimen validity testing, CPS's overall UDS policies resulted in submitting claims for an array of medically unnecessary testing, including but not limited to, duplicative drug tests, quantitative tests that were not medically necessary and often done even when the urine was negative for drugs, and upcoding for Modifier 59.

208. Some examples are as follows:

a. Carrero submitted a claim to Medicare on November 9, 2011 on patient S.B. under CPT codes 81003 (automated urinalysis) with a Modifier 59 code, 84311 (chemical analysis using spectrophotometry) with a Modifier 59 code, and G0431 (qualitative testing), for which Medicare paid CPS a total of $118.48. CPS also was paid for specimen validity testing that Carrero submitted on this patient.

b. Kroll submitted a claim to Medicare on November 16, 2011 on patient D.M. under CPT codes 81003 (automated urinalysis), 84311 (chemical analysis using spectrophotometry), and G0431 (qualitative testing), for which Medicare paid CPS a total of $115.32. CPS also was paid for specimen validity testing that Kroll submitted on this patient.

c. Dickerson submitted a claim to Medicare on December 1, 2011 on patient C.P. under CPT codes 81003 (automated urinalysis), 84311 (chemical analysis using spectrophotometry), and G0431 (qualitative testing), for which Medicare paid CPS a total of $115.32. CPS also was paid for specimen validity testing that Dickerson submitted on this patient.

d. Dickerson saw an established patient, T.C., on July 24, 2014 for an injection. He submitted his urine for testing on July 25, 2014, which included tests for under CPT code 82055 (alcohol), 84311 (chemical analysis using spectrophotometry), and G0431 (qualitative testing), for which Medicare paid CPS a total of $123.48. CPS also was paid for specimen validity testing that Dickerson submitted on this patient.

e. On August 5, 2014, Dickerson submitted claims for additional urine drug testing on patient T.C., which included tests for PCP under CPT code 83992, a generic test for opiates under CPT code 83925, methadone under CPT code 83840, cocaine under CPT code 82520, and two broad panels of testing under CPT codes 82542 and 83789, in addition to other tests. The total amount Medicare paid CPS for the August 5, 2014 urine tests on patient T.C. was $426.12.

f. Less than two months later, on September 19, 2014, Dickerson's patient, T.C., had another round of UDS performed, for which Dickerson submitted claims under CPT codes 82055 (alcohol), 84311 (chemical analysis using spectrophotometry) and G0431 (qualitative testing), and for which Medicare paid CPS a total of $121.02. CPS also was paid for specimen validity testing that Dickerson submitted on this patient.

g. Dickerson also submitted multiple claims for UDS for patient B.A. in April, June, July, August, and September 2012. Such amount of testing is far in excess of what is medically necessary.

209. As of 2016, CPS would file a claim for reimbursement under CPT code G0483, which was quantitative testing. The reimbursement rate at that time was $210.93.

210. Below are some examples of patients who Smith has admitted tested negative for drugs and yet CPS performed quantitative testing on their urine, which lacked medical necessity:

a. On or about August 16, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

b. On or about September 13, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

c. On or about October 11, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for

beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

d. On or about November 3, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

e. On or about December 2, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

f. On or about January 5, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

g. On or about March 1, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary B.E. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

h. On or about November 10, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary D.B. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

i. On or about January 11, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary D.B. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

j. On or about February 9, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary D.B. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

k. On or about March 6, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary D.B. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

l. On or about March 30, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary D.B. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

m. On or about August 5, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary C.R. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

n. On or about October 4, 2016, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for

beneficiary C.R. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

o. On or about January 6, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $210.93 for a claim CPS submitted for beneficiary C.R. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.

p. On or about March 3, 2017, in an East Tennessee CPS clinic for which Smith had oversight, Medicare paid CPS $248.79 for a claim CPS submitted for beneficiary C.R. under CPT code G0483 for a CDDP panel, even though the screening for all drug classes came back negative.[6]

211. Had the Federal Health Care Programs and TennCare known that the quantitative testing was not medically necessary or that CPS providers otherwise lacked the requisite medical documentation, they would have denied payment for these claims.

212. To ascertain the full extent of damages to the Federal Health Care Programs and TennCare for CPS's overuse of UDS, it is necessary to review additional patient records.

2. Genetic Testing

213. In addition to the excessive urine testing, in or about May 2013, CPS began performing pharmacogenetic blood testing on patients, which purportedly screened for variations in genes to determine how quickly a patient might metabolize pharmaceutical drugs.

[6] These examples were a part of the allegations that Smith included in the *qui tam* complaint he filed against CPS, which alleged false claims relating to UDS. The United States declined to intervene in that action, which was voluntarily dismissed.

214. Upon information and belief, Defendants knew or should have known that the genetic testing CPS and its providers were performing was not reimbursable by the Federal Health Care Programs or TennCare.[7]

215. The Federal Health Care Programs and TennCare only reimburse for certain genetic testing when medically necessary under the non-specific procedure CPT codes 81225, 81226, 81227, 81355 and 81401, which are the same CPT codes CPS used to bill for its genetic blood testing.

216. However, during the relevant time period, for testing to be medically necessary for CPT code 81225, the patient must have had acute coronary syndrome (ACS) and have been undergoing percutaneous coronary interventions with Plavix therapy. Cahaba LCD for Pathology and Laboratory: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing, L35660, effective October 1, 2015. Absent these conditions, Cahaba did not cover the testing, as stated in its LCD: "There is insufficient evidence to demonstrate that genetic testing for CYP2C19 gene improves clinical outcomes. Consequently, genetic testing for the CYP2C19 gene outside of the specified covered indications is considered investigational." Wisconsin Physician Service also provided for similar limited use. (L36398)

217. For CPT code 81226, the patient must have had planned treatment for depressive disorders with amitriptyline, nortriptyline or tetrabenazines.

[7] When CPS providers took blood for this non-reimbursable pharmacogenetic testing, they also performed a battery of tests under the guise of a Health and Wellness Panel, including hormone, thyroid and vitamin levels, for which mid-level providers were bonused. Upon information and belief, this testing was done to increase the amount of reimbursement from the Federal Health Care Programs and TennCare to CPS, and such testing was medically unnecessary and unrelated to the patient's treatment, which typically was for pain relief.

218. For CPT codes 81227 and 81355, NCD 90.1, effective August 3, 2009, stated that pharmacogenomic testing to predict Warfarin responsiveness was investigational and not considered reasonable or necessary under the Act and not covered. Further, there needed to be a plan to treat the patient with Warfarin and other strict guidelines must have been met, including being enrolled in a clinical study.

219. For CPT code 81401 to be considered medically necessary, the patient must have had medical documentation showing long term use of opioids, the response to such opioids that included either a failure to respond to opioid treatment or some diminished reactions to treatment, as well as an explanation of how the testing was expected to benefit the patient's treatment. The documentation also needed to note how a change in medication would reflect the outcome of the testing.

220. The average Medicare allowed amount for these CPT codes varied, but typically ranged from approximately $150 to $320 per test.

221. Upon information and belief, in all but the rarest of cases, CPS lacked any medical necessity for performing these genetic tests, and certainly had no basis to do so at the outset of treating a patient.

222. Further, CPS did not maintain the required supporting documentation, let alone utilize the results of these tests when considering treatment options for its patients. Instead, CPS advised providers to use "a stock statement" in its EMR system to provide a description of medical necessity.

223. As of at least November 19, 2013, CPS also provided a $25 bonus as an incentive to mid-level providers to order genetic testing that was to be performed at CPS's testing facility.

224. When the number of claims for genetic testing did not meet Davis's expectations, CPS sent emails to remind providers not to miss out on this billing opportunity. On August 15, 2014, Jeff Hurst emailed providers outlining the various genetic testing options and explained: "Cytochrome P450 tests (CYP450 tests) are used to help determine how the human body processes (metabolizes) a drug. Humans contain numerous P450 enzymes to metabolize medications. Because of genetic variations in these enzymes, medications affect each person differently." He then advised: "By checking patient's DNA for certain gene variations, cytochrome P450 tests can offer clues about how the body may respond to a particular drug." Notably absent from the email is any indication of when it is medically necessary to test patients to determine their ability to metabolize drugs.

225. CPS's Education Department eventually published Genetic Testing Guidelines, effective October 1, 2014, which also were sent to new providers as they joined. A factor for genetic testing "included populations at increased risk for adverse events: elderly, COPD or other co-morbidities, immunocompromised, chronically ill." Despite urging providers to order genetic testing, CPS claimed conveniently that it was not directing providers to utilize this "service."

226. Ultimately, Davis's pressure to perform genetic testing was successful. On August 20, 2015, an internal CPS audit found excessive ordering of genetic testing on patients for which there was no medical necessity documented. Some CPS providers were even ordering and billing for genetic testing on every new patient, regardless of the fact that there was no medical documentation that could possibly support that submission of claims under the relevant CPT codes that CPS was using.

227. Moreover, the ZPIC audit expressly flagged genetic testing as a problem. Despite CPS's many appeals of the ZPIC determination, it still was unable to obtain a favorable result with

respect to the genetic testing, as set forth in the September 1, 2016 Medicare Reconsideration Decision.

228. Specifically, the QIC concluded that there was insufficient medical documentation and no medical necessity for CPS to conduct the genetic testing on the patients it sampled.

229. Through its internal investigation in response to the ZPIC audit, CPS was aware of an overutilization of genetic testing at its East Tennessee clinics in Oak Ridge, Maryville and Lenoir City, for which Dr. Donald Jones was the supervising physician. Interestingly, Dr. Jones had a financial arrangement with CPS, whereby he was paid ninety percent of his revenues collected, which included his self-referrals, and CPS received the remaining ten percent.

230. On November 3, 2015, Amy Turner, the Director of Clinical Education for CPS, and Sarah Trent, who was Director of Quality Assurance at that time, met with providers in Oak Ridge, including Dr. Jones, to provide training on genetic testing. During the training, the Oak Ridge providers confirmed that it was their standard practice to order genetic testing on every new patient, and that the results of the testing rarely were utilized.

231. That same day, Pam Arnold and Erin Galloway also provided training to CPS providers in Maryville and Lenoir City, Tennessee, who also had previously been conducting genetic testing on all new patients. Providers were instructed that new patients typically should not be tested genetically, and that such testing was more beneficial on follow up visits when there was medical documentation that may support the genetic testing. Providers also were told to document medical necessity for both genetic testing and UDS.

232. The assessments from the East Tennessee training sessions were sent to Davis and Kroll on November 11, 2015, and at least Kroll reviewed the results provided to him and was fully aware of the practice of excessive genetic testing in these clinics.

233. Despite the training, at a May 13, 2016 Compliance Committee meeting, which Kroll and Davis attended, the issue was raised that genetic testing still was being done on every patient, which needed to be stopped.

234. Thus, even though CPS knew that (i) genetic testing generally was not reimbursable for virtually all of CPS's patients; (ii) the QIC found the claims submitted for genetic testing to be non-reimbursable and lacking the requisite medical documentation; and (iii) CPS's own internal investigation concluded providers were performing excessive testing, CPS continued to fraudulently bill the Federal Healthcare Programs and TennCare for genetic testing from 2013 to it ceased operating in 2018.

235. Moreover, although CPS acknowledged that genetic testing can only be performed once per patient, at least three patients had their DNA checked more than once, for which there is no medical necessity.

236. Specifically, CPS billed TennCare for genetic testing on patient J.C. under CPT codes 81401 and 81226 on May 14, 2013, for which it was paid $576.00 and again on June 18, 2014, for which it was paid $600.00.

237. CPS also billed TennCare for genetic testing on patient C.M. under CPT codes 81401 and 81226 on August 29, 2013, for which it was paid $576.00 and again on October 15, 2013, for which it was again paid $576.00.

238. In addition, CPS billed TennCare for genetic testing on patient M.H. under CPT codes 81401 and 81226 on October 25, 2013, for which it was paid $460.00 and again on January 20, 2014, for which it was again paid $460.00.

239. From 2013 to 2018, the United States paid CPS approximately $2 million for 3,805 claims submitted to Medicare with 11,738 claim lines for genetic testing under CPT codes 81225,

81226, 81227, 81355 and 81401. Of this amount, $131,054.74 is attributable to Kroll for 454 claims and 1,852 claim lines; $2,143.14 to Dickerson for 5 claims and 13 claim lines; and $4,170.52 to Carrero for 6 claims and 23 claim lines.

240. Some examples of the false claims that CPS and the Owners submitted for genetic testing are as follows:

a. CPS billed Medicare for genetic tests performed on patient M.R. on August 14, 2013 under CPT codes 81225, 81226, 81227, 81355 and 81401 with Modifier 91, which lists Kroll as the Rendering Provider, for which it was paid a total of $759.50.

b. CPS billed Medicare for genetic tests performed on patient W.W. on August 14, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Kroll as the Rendering Provider, for which it was paid a total of $1,045.54.

c. CPS billed Medicare for genetic tests performed on patient L.V. on August 14, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Dickerson as the Rendering Provider, for which it was paid a total of $1,045.54.

d. CPS billed Medicare for genetic tests performed on patient R.S. on September 9, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Carrero as the Rendering Provider, for which it was paid a total of $1,045.54.

e. CPS billed Medicare for genetic tests performed on patient E.G. on September 16, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91,

which lists Dickerson as the Rendering Provider, for which it was paid a total of $1,045.54.

f. CPS billed Medicare for genetic tests performed on patient D.T. on September 16, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Carrero as the Rendering Provider, for which it was paid a total of $1,045.54.

g. CPS billed Medicare for genetic tests performed on patient M.B. on September 30, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Dickerson as the Rendering Provider, for which it was paid a total of $1,045.54.

h. CPS billed Medicare for genetic tests performed on patient M.T. on September 30, 2014 under CPT codes 81225, 81226, 81227 and 81401 with Modifier 91, which lists Carrero as the Rendering Provider, for which it was paid a total of $1,045.54.

i. CPS billed Medicare for a genetic test performed on patient A.J. on August 4, 2015 under CPT code 81401 with Modifier 91, which lists Carrero as the Rendering Provider, for which it was paid a total of $274.40.

j. CPS billed Medicare for a genetic test performed on patient M.J. on April 12, 2017 under CPT code 81401 with Modifier 91, which lists Kroll as the Rendering Provider, for which it was paid a total of $274.40. Patient M.J.'s address is listed as North Carolina.

k. CPS billed Medicare for a genetic test performed on patient C.R. on April 25, 2017 under CPT code 81401 with Modifier 91, which lists Kroll as the

Rendering Provider, for which it was paid a total of $274.40. Patient C.R.'s address is listed as Illinois.

3. Psychological Testing

241. As another means of revenue, in or about 2012, CPS also began performing psychological testing on patients purportedly to determine whether they were at risk of issues with addiction, depression or suicidal thoughts using iPads for which it would bill the Federal Health Care Programs and TennCare under CPT code 96103.

242. Upon information and belief, Defendants knew or should have known that the type of psychological testing CPS and its providers were performing was not reimbursable by the Federal Health Care Programs or TennCare.

243. The Federal Health Care Programs and TennCare only reimburse for certain psychological testing if it is medically necessary under CPT code 96103. The Medicare reimbursement for CPT code 96103 ranged from $19.88 to $50.43 per test during the relevant time period.

244. CPS also was aware that private insurers did not reimburse for psychological testing performed on an iPad by a provider that was not treating mental health issues, as there was not deemed to be any medical necessity.

245. Some CPS providers felt that there was no medical necessity for the iPad tests because there were no substantiated means of measuring the effectiveness of the testing. Further, CPS lacked a response protocol in the event psychological issues were identified. In fact, as of January 14, 2013, CPS had no plan in place regarding suicidal ideation. Upon information and belief, CPS never implemented any formal policy as to how to respond to the results of the iPad testing.

246. Instead, it gave mid-level providers a $5 bonus as an incentive for ordering the iPad testing.

247. In an effort to support a basis for reimbursement from the Federal Health Care Programs and TennCare, CPS's billing department also would review progress notes and adjust diagnoses to justify a purported medical necessity for this psychological testing (*i.e.*, finding that trouble sleeping was insomnia that could lead to depression).

248. Then to ensure that more providers would bill for this testing, CPS negotiated a flat rate with its vendor so that "ALL" patients could be tested, regardless of whether their insurance covered the cost of the test. At Davis's behest, Sarah Trent, who had taken on the role of CPS's Education Coordinator, sent an email on January 20, 2014 to all CPS providers, advising them to "continue to submit the 96103 code regardless of insurance carrier." She noted, however, that if the test was "not covered, then it will not be represented on your incentive." This was nothing more than an altruistic guise designed to ensure that providers would utilize the testing so that CPS could capture this revenue whenever it was reimbursed.

249. The highest number of iPad tests administered during the January and February 2015 period was 2,150 from the Oak Ridge, Tennessee location, which was operated by Dr. Jones, who acknowledged he was receiving ninety percent of the revenue he collected from these tests.

250. On March 24, 2015, Kim Pennington, CPS's Director of Site Operations, emailed CPS Managers concerning a decline in iPad testing. She noted that if providers did not utilize such testing, Davis would be asking them why during their evaluations. She further stated: "Quarterly bonuses may be negatively affected as well." She then advised that Ms. Trent would be sending providers an email about iPad testing as well.

251. The next day, March 25, 2015, Sarah Trent, who at that time had taken on the role of CPS's Director of Clinician Education, sent out an email to CPS providers at Davis's insistence and with Kroll's approval, reminding them to use the iPad tests and noting that it could either assist with bonuses or "negatively impact" them if they failed to utilize this "tool."

252. On December 7, 2015, at Davis's direction, Ms. Trent again advised staff that it was standard practice to employ iPad testing on patients and "non-participation would not be accepted any longer."

253. In fact, CPS was so intent on capturing this revenue stream that in some instances, it was billing for these tests under Kroll, even though he was not the rendering physician. It is unclear whether all of these tests occurred or if they were simply billed incorrectly.

254. Dickerson became aware of the practice of billing under Kroll's NPI in September 2016. Yet, Dickerson failed to report the issue to the Federal Health Care Programs or TennCare.

255. Regardless of who the tests were billed under, CPS was aware from the ZPIC audit that they should not have been billing for them. Even with CPS's appeals, in the September 1, 2016 Medicare Reconsideration Decision, the QIC noted that some of the patients were under the care of a psychiatrist, and did not require this testing, let alone the number of tests performed.

256. Yet, from 2012 to 2018 when it ceased operating, CPS billed for its iPad testing under CPT code 96103, for which Medicare alone paid CPS over $2.4 million for 145,767 claims.

257. Of this amount, $34,656.28 is attributable to Kroll for 1,115 claims; $11,983.01 to Dickerson for 491 claims; and $11,820.24 is attributable to Carrero for 442 claims.

258. Some examples of the false claims CPS and the Owners submitted for iPad testing under CPT code 96103 are as follows:

a. CPS billed Medicare for an iPad test performed on patient R.K. on December 11, 2012 under CPT code 96103, which lists Kroll as the Rendering Provider, for which it was paid $46.13.

b. CPS billed Medicare for an iPad test performed on patient K.J. on June 6, 2013 under CPT code 96103, which lists Dickerson as the Rendering Provider, for which it was paid $50.43.

c. CPS billed Medicare for iPad tests performed on patient P.E. on November 11, 2016 and December 9, 2016 under CPT code 96103, which list Dickerson as the Rendering Provider, for which it was paid $19.88 on each claim.

d. CPS billed Medicare for an iPad test performed on patient S.C. on December 7, 2016 under CPT code 96103, which lists Kroll as the Rendering Provider, for which it was paid $19.88.

e. CPS billed Medicare for iPad tests performed on patient C.K. on January 1, 2017 and February 14, 2017 under CPT code 96103, which list Carrero as the Rendering Provider, for which it was paid $20.77 on each.

f. CPS billed Medicare for an iPad test performed on patient M.O. on April 13, 2017 under CPT code 96103, which lists Kroll as the Rendering Provider, for which it was paid $20.92.

g. CPS billed Medicare for iPad test performed on patient S.B. on March 19, 2018 under CPT code 96103, which lists Dickerson as the Rendering Provider, for which it was paid $20.83.

h. CPS billed Medicare for an iPad test performed on patient C.H. on May 21, 2018 under CPT code 96103, which lists Carrero as the Rendering Provider, for which it was paid $20.83.

i. CPS billed Medicare for an iPad test performed on patient S.C. on June 12, 2018 under CPT code 96103, which lists Dickerson as the Rendering Provider, for which it was paid $20.83.

B. CPS Incentivizes Providers To Order Medically Unnecessary Services

259. To ensure that providers were increasing CPS's revenues from the various tests and procedures that could be billed, as well as for DME, CPS developed a plan whereby its employees would be incentivized to order as many tests and other ancillary services as possible on each patient.

260. In or around 2012, CPS adopted an initiative whereby mid-level providers (*i.e.*, nurse practitioners and physician assistants) could qualify for bonus compensation in addition to their fixed salaries. The bonus was calculated based on the ancillary services ordered for CPS's patients. Such ancillary services include sleep studies, EMGs, ultrasounds, injections, spinal cord simulator trials, transcutaneous electrical nerve stimulation ("TENS") units, back braces and other DME. Over time the bonusable items expanded to include certain clinical laboratory tests, including UDS, genetic testing, iPad psychological testing, and Health and Wellness Panels, as well as compound creams, and procedures, such as pulse stimulation treatments (so-called "P-Stims"). The bonus amounts ranged from $5 for an iPad test to $150 for a spinal cord stimulator trial.

261. The bonus amounts changed over time, with revisions to the policy on November 19, 2013, October 27, 2014 and December 22, 2014.

262. Bonuses were calculated based on monthly spreadsheets reflecting the volume of ancillary services that mid-levels submitted primarily to Davis, as CEO, or Shannon Skipper, a Vice President of Business Development for CPS.

263. Critically, no bonus would be paid unless the service was "***completed***" and "***in-house***/with CPS." (emphasis in original email)

264. The policy incentivized providers to order medically unnecessary services. Per a November 4, 2013 email from Michelle Cook, an Office Manager with CPS, to Ms. McGhee, several CPS employees were aware that one mid-level provider was "gearing the majority of her decision making based on what she can get a bonus on."

265. Ms. Trent also has acknowledged that mid-level providers ordered ancillary services that were not medically necessary because of CPS's bonus structure and pressure put on them expressly by Davis and Smith.

266. In addition to the mid-levels, physicians also were incentivized to increase revenue to CPS through their respective employment or independent contractor agreements, which provided them with compensation based on net revenues collected, as well as a separate component that was based on the amount of money CPS realized from the ancillary services that both physicians, and the mid-levels they supervised, ordered. However, the services must have been ordered through CPS to qualify for the bonus. The ancillary services revenue then would be distributed to the Owners, the physicians and the mid-levels based on a calculation that Davis determined.

267. For example, CPS had an Employment Agreement with Paul Pinson, M.D., dated June 27, 2013, which was signed by Dickerson as President of CPS. Pursuant to this agreement, CPS paid Dr. Pinson $37,500 monthly, in addition to a bonus purportedly based on "overall

productivity of the medical office where Physician provides service." Dr. Pinson was employed at the Cleveland, Tennessee clinic that Smith oversaw.

268. In an "Independent Contractor Agreement" between CPS and Dr. Brummett, dated March 27, 2014, the compensation was set at fifty percent of all revenue collected, plus ten percent of those he supervised for the first year. It increased to fifty-five percent of his revenue in the second year, and sixty percent in the third year. In the third year, his share of revenues for his mid-levels increased to fifteen percent. In addition, Dr. Brummett received a share of ancillary services revenue, with fifty percent of the revenues generated contributed to the pool for non-Owners and the other fifty percent to CPS, and thus, the Owners.

269. Dr. Buenger's agreement, dated April 3, 2014, provided for fifty percent of the revenue collected, plus ten percent of the revenue collected by providers he supervised in the first year or a draw of $30,000 a month, whichever was greater. In the second year, he received fifty-five percent of his revenues, which increased to sixty percent in the third year. In addition, he received a share of the ancillary services revenue, which included the services his mid-levels ordered.

270. Relator Dr. Suzanne Alt's employment agreement with CPS, which dated May 26, 2014 and signed by Davis, entitled her to fifty percent of revenues collected in the first year, and an additional ten percent of revenues collected for those she supervised in her second year. She also was entitled to a share of the ancillary services revenue, similar to Dr. Buenger's agreement, but with a draw of only $27,000.

271. CPS also entered into an agreement with Dr. Cynthia M. Niendorff, dated November 12, 2015, which was signed by Davis, whereby she received only thirty percent of the revenue collected from services she personally provided in the first year, and an additional ten

percent of all revenue collected from services rendered by nurse practitioners and physician assistants under her supervision, which included Anita Bayles. She also was entitled to a share of the ancillary services revenue, the calculation of the amount of which was not specified. In addition, she received a salary of $39,500 per month for providing services at the Cleveland and Chattanooga, Tennessee locations. If she only provided supervisory services at the Cleveland location, it was reduced to $19,750 per month. Smith oversaw the clinics in which Dr. Niendorff worked.

272. CPS physicians also were compensated for referrals to CPS's pharmacy and encouraged to use CPS's pharmacy to fill prescriptions, especially for compounding creams, which was an item for which their mid-levels would receive bonuses. The referrals for CPS pharmacy items were included in the ancillary services revenue that was a part of the physician compensation.

273. On October 7, 2014, Dickerson emailed Davis to note that some mid-levels were complaining about their compensation, as new patients presented more bonus potential than established patients. In response, Davis turned the complaint into an opportunity to remind the Owners how much money they were making, which he attributed in part to the new hires, who followed his protocol of ordering a full panel of UDS, with specimen validity testing, genetic testing, pain creams, wellness blood panels and other ancillary services that increased per patient revenue.

274. In January 2015, as the greed of the Owners and Davis grew, CPS modified its mid-level bonus policy to provide for a monthly draw based on the average of the providers' bonuses for the preceding three months, as well as for a variable quarterly bonus based on the volume of new patients, follow-up visits and procedures ordered, and quality reviews from the provider's

manager or supervising physician. Bonuses could be adjusted downward if the mid-level was not ordering all the ancillary services available.

275. By June 2015, Carrero noted that this resulted in mid-levels being scheduled to see more patients so that they would have more opportunities to receive bonuses by providing ancillary services, while his patient schedule had diminished.

276. Davis advised Carrero and Dickerson that their diminished revenues were based on a purported decline in their ordering of UDS, EMGs, Level 4 follow up visits, and iPad testing in 2015, as compared to 2014. However, Carrero and Dickerson did not agree with this assessment.

277. As of July 2015, Dickerson and Carrero began questioning the veracity of the billing information. When they did not obtain the answers they wanted from Davis, they did not push any further, being content with the ultimate amounts CPS was paying into their bank accounts.

278. In the meantime, the mid-levels continued to complain that bonuses were based solely on revenue, without even seeking input from the physicians who were supervising the mid-levels.

279. At a meeting of the Board of Directors on November 2, 2016, which included Kroll and Dickerson, as well as Davis, a new bonus compensation plan was approved for 2017 that applied to all clinic staff except physicians.

280. On November 15, 2016, a nurse practitioner sent an email to Dickerson and Carrero expressing the concerns of mid-levels about the evaluation process, which impacted quarterly bonuses. She expressly noted that CPS providers had been asked "to perform unethical practices activity on charts." The examples included Level 4 follow up visits, UDS, blood testing, and DME.

281. Once this complaint made its way to the Board of Directors and the Owners, CPS again changed the way it calculated bonuses, but it did not address the ethical problems raised in the email.

282. CPS also did not stop Smith's financial arrangement, which incentivized him to have the providers in his clinics order more UDS and ancillary services as compared to other CPS locations. CPS, Davis and the Owners also were aware that Smith was pressuring his providers to order these tests and DME when it was not medically necessary.

283. Specifically, in or around June of 2017, CPS was aware that Smith was attempting to influence the clinical decision-making of providers.

284. Yet, Davis and the Owners did nothing to stop the fraudulent conduct and failed to notify the Federal Health Care Programs or TennCare of any overpayment.

285. On June 27, 2017, CPS terminated Smith's employment for cause.

286. Thus, from at least 2013 until CPS ceased operating in 2018, Defendants directly, and through their agents, physicians and mid-level providers, managers, and employees, systematically pressured CPS's medical providers and incentivized them with a bonus policy to increase the per patient revenue, which resulted in unnecessary medical testing, procedures, and prescriptions for DME and other ancillary services.

C. Fraudulent Billing Related To Acupuncture

287. CPS also fraudulently billed the Federal Health Care Programs and TennCare for acupuncture on the ear, which is unequivocally not reimbursable.

288. In October 2013, Waymond "Bo" Boyer, CPS's Vice President of Business Development, Skipper and Davis began working with external consultants, including Corthomed, to implement the use of acupuncture on patients through a device referred to as a P-Stim.

289. In November 2013, working with Kevin Jones of Recipion Healthcare Consulting and Lisa Fontenot of Dumme Xchange, LLC, CPS, through Davis and Boyer, created a "PStim launch team" designed to market "PSTIM™"a small, discreet device applied behind a patient's ear that "provides a steady current of low frequency electrical impulses," of which Kroll was fully informed.

290. CPS's internal documents show that pulse stimulation treatment is "blending conventional acupuncture therapy with scientific technology," with a treatment plan that consisted of three weekly sessions and a rest period. It incorrectly states that Medicare provides coverage, although it makes clear that the device was not implantable or done on a trial basis to determine whether an implant would be therapeutic.

291. Indeed, a National Coverage Determination ("NCD") for Acupuncture (30.3) states "acupuncture is not considered reasonable and necessary" within the meaning of Section 1862(a)(1) of the Social Security Act (the "Act"). This is a long-standing determination and was widely known throughout the relevant time period, and at least prior to April 16, 2004. Thus, CPS was fully aware that acupuncture, in any form, was not reimbursable by the Federal Health Care Programs or TennCare.

292. To circumvent the prohibition against coverage for acupuncture, when CPS placed a percutaneous auricular neurostimulator device with needles on its patients, which was referred to internally as P-Stims, CPS, working with its external consultants, billed Medicare using any code that might result in the claim being paid.

293. The primary code that CPS used to bill for acupuncture was HCPCS Code L8680, which was in effect from January 1, 2006 through March 31, 2014, and was intended to cover the actual cost of each implantable neurostimulator electrode for trials, and if therapeutic, also could

be used to seek reimbursement for the cost of the procedure. As of April 1, 2014, Medicare no longer paid out under this code, which was not intended to cover P-Stims or any other type of acupuncture. [As of January 1, 2014, L8679 was used for implantable neurostimulator, pulse generator, any type.]

294. However, for the Federal Health Care Programs and TennCare to reimburse for L8680, a device must actually be *implanted* in a patient, typically in the lumbar region, which requires a surgical setting. The P-Stim devices, to the contrary, were placed on the ear and were not implanted in this manner.

295. Nor could they be considered electrical nerve stimulators. In fact, the NCD for Electrical Nerve Stimulators (160.7), which was effective August 7, 1995, states with respect to implanted peripheral nerve stimulators: "Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room."

296. A later NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1), effective June 19, 2006, provided further guidance with respect to nerve stimulation that is transcutaneous (TENS) and percutaneous (PENS). For TENS, the device is attached "to the surface of the skin over the peripheral nerve to be stimulated," and "is used by the patient on a trial basis." For PENS, the diagnostic procedure involves a "needle electrode inserted through the skin" and is "covered only when performed by a physician or incident to physician's service." Both TENS and PENS are intended to be used on a trial basis, typically one month, to determine whether an implanted nerve stimulator would provide therapeutic benefit.

297. The same NCD further states: "Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage

by § 1862(a)(1) of the Act." Thus, P-Stims could not be billed for and reimbursed as either TENS or PENS.

298. Davis was well aware that the L8680 code "is related to an implant which is done by MD's." The Owners, who were certified as anesthesiologists, also were capable of performing and did perform spinal cord stimulator trials, which were the procedures meant to be covered by this code. Thus, CPS, Davis and the Owners knew or should have known aware that CPS should not have been billing for the P-Stims under L8680, and that mid-levels should not have been able to perform the procedure.

299. Yet CPS was ramped up to perform and bill for as many of these P-Stims as possible. Davis even tracked billings on a weekly basis for some providers to ensure sufficient inventory to meet patient demand.

300. Of course, almost immediately CPS ran into problems with coverage denials for these P-Stims, which prompted much discussion internally, as well as with the external reimbursement consultant, Dragon Slayer Strategies.

301. After consultation, on or about November 18, 2013, CPS created a template for "P-Stimulator Placement" in eCW that pulled CPT Code 64555 "IMPLANT NEUROELECTRODES" and L8680 "IMPLT NEUROSTIM ELCTR EACH" to direct how CPS providers should bill for the acupuncture. Kroll was copied on this email.

302. In place of code 64555, CPS eventually decided to use CPT Code 64999, which is for Unlisted Procedure, nervous system.

303. After code 64999 also resulted in claims being denied, CPS next used CPT Code 64550, which is for TENS NEUROSTIM, apparently trying to rationalize that the "device was

applied via a transcutaneous approach versus a percutaneous application." This code was employed in addition to the L8680 code.

304. CPS's conduct in continuing to try to find ways to seek reimbursement from the Federal Health Care Programs and TennCare for the P-Stims is all the more glaring given that as of late November 2013, CPS's billing department knew that P-Stim was acupuncture, which was not reimbursable under any code.

305. On November 22, 2013, Beverly ("Brooke") Russell, a Billing Manager for CPS, sent a query to Palmetto, the MAC for the North Carolina region at that time, seeking guidance concerning coverage for the P-Stim device. Ms. Russell expressly stated that CPS was "doing a procedure that involves the P-stim Device" and noted the "many debates on the codes to bill." She explained that the "needles are only in the ear for 4 days, then [CPS will] implant another one." Her concern was whether to follow CMS or FDA guidelines on the definition of "implant" as far as coverage was concerned, as the FDA required that the implant "remains in the body for 30 days."

306. In response, on November 27, 2013, Palmetto made clear that the "P-Stim Device" was "a form of acupuncture which is not considered reasonable and necessary within the meaning of § 1862(a)(1) of the Act." Thus, CPS was well aware that it should not be seeking reimbursement for P-Stims.

307. Yet, CPS continued to attempt to bill the Federal Health Care Programs and TennCare for the P-Stims.

308. On December 4, 2013, Ms. McGhee questioned why CPS was using 64999 for "Pstim placement" when it was listed as nervous system *surgery* in the CPT book.

309. On December 17, 2013, Davis notified internal CPS personnel responsible for billing to email him every time that Medicare denied the L code for PSTIM. He advised that they should bill for "incident to" wherever possible when the supervising physician is in the office, which he noted was less often the case. He further advised Boyer to contact the PSTIM representatives to address the billing issues. For one claim specifically that Medicare denied because it was billed under a nurse practitioner, Davis advised to resubmit it under the supervising physician, Dr. Pinson.

310. On January 28, 2014, Davis emailed CPS physicians, including the Owners, that Medicare denied P-STIM procedures that were coded under 64999 as not medically necessary.

311. As of February 5, 2014, at least some November 2013 claims were being held to confirm the location of the placement of the P-Stim, which was auricle – and not on the lumbar, as is required for the L8680 code.

312. Recognizing that physicians were not typically in the office, CPS needed an alternative way to bill. On February 17, 2014, CPS made the decision to use code 64550 for P-Stim procedures and edited the description in the billing template to replace the word percutaneous with the word transcutaneous.

313. Following this decision, on February 20, 2014, Ms. McGhee sent a memo to CPS physicians, including the Owners, with a copy to Davis, with the subject of P-STIM Denials. She noted that a "large number of claims are being denied for P-STIM procedures" because the documentation did not indicate that it was a "transcutaneous approach versus a percutaneous application" – essentially a "TENS NEUROSTIM" – instead she indicated that billing under 64999 should be re-submitted under 64550.

314. In that email, Providers also were told to add the following language:

> PSTIM device was applied transcutaneous using the multipoint stylus to identify skin points with diminished electrical resistance, three points were identified, and the skin at each point was marked. Needle electrodes were placed transcutaneous, overlying the exterior ear using sterile technique at each of the aforementioned marked areas and secured with their securing tape. The P-Stim pulse generator device itself was placed just inferior and posterior to the ear in the areas of the mastoid and the lead wires extending posterior behind and over the top of the ear. The patient reported the onset of stimulation almost immediately.

315. On March 19, 2014, Ms. McGhee emailed Kroll questioning how to bill for P-Stims in light of new NCD and LCDs. She specifically asked for a review of information sent by the medical device sales representatives who "are not as transparent with the recommendation of allowable billing codes."

316. As of March 25, 2014, CPS changed its eCW template to reflect the transcutaneous language with a revision to codes 64550 and L8680 to ensure billing would be consistent.

317. Eventually, the coding submission game ended, as Medicare communicated that effective April 1, 2014, it would no longer reimburse under the L8680 code for the cost of the device in conjunction with office-based trials, as that cost was subsumed with the submission of claims under CPT code 63650.

318. Following that announcement, in a March 31, 2014 email from Ariane Keller, the HR Assistant Manager, CPS abruptly communicated to all its providers: "Effective immediately CPS will no longer be administering P-Stim therapy … due to very recent changes in Medicare."

319. That same day, Ms. Trent also emailed providers, including the Owners, copying Davis, that CPS was "NO LONGER ABLE TO DO P-STIMS" due to "recent CMS changes." She also noted that it was "effective immediately" and that "ALL pending P-STIMS are to be CANCELLED as of now."

320. Thus, CPS acknowledged that it should not be billing Medicare going forward and also that it was providing a "therapy" as opposed to an implantable device.

321. In addition, because Medicare often denied CPS's P-Stim claims because the documentation was insufficient, CPS knowingly continued to resubmit these false claims even after March 31, 2014.

322. Eventually, CPS's compliance personnel realized that Medicare had never covered the cost of this acupuncture, and CPS conducted an internal audit to review the submission of claims from November 2013, when the P-Stim devices were "launched," as described in Davis's email, until mid-2014.

323. On July 18, 2014, Relator Jennifer Pressotto, the Director of Corporate Compliance for CPS, noted that Medicare did not provide payment for the P-Stims that CPS was doing at least as of 2013.

324. In a document entitled "P-Stim Compliance Team Review," dated July 17 and 18, 2014, CPS's compliance personnel noted that "If Medicare does not cover this procedure, it doesn't matter how it is coded, we need to refund the money."

325. Internal CPS personnel determined that it was appropriate to refund 64555 with L8680 and all L8680 billed with 64550 and 64999.

326. Compliance determined to keep the monies related to 64999 and 64550.

327. On or about July 28 and 29, 2014, internal CPS compliance personnel, including Ms. Pressotto, met to review the P-Stim data and determine an Action Plan to present to Davis for his approval.

328. In a document entitled "P-Stim Compliance Team Review July 28 & 29, 2014 Findings and Plan of Action," the compliance team determined: "Any codes specific to the P-Stim

procedure should be refunded" to Medicare, Medicaid and other payers. These codes were 64999, 64550, 64555, L8680, 95921, and 95970. At that time, CPS determined that the payment received on over 200 claims should be refunded to the Federal Health Care Programs and TennCare, the amount of which totaled $136,016.97.

329. The Owners knew or should have known about the false submission of claims for acupuncture, as they directly engaged in the wrongful conduct.

330. Some examples of the false claims CPS and the Owners submitted to the Federal Health Care Programs and TennCare for acupuncture are as follows:

a. On November 12, 2013, Kroll performed acupuncture on patient E.B., for which CPS submitted a claim to Medicare under codes L8680 and 64555 and was paid a total of $5,419.51, which CPS and Kroll should have refunded.

b. On November 13, 2013, Carrero performed acupuncture on patient D.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,025.91, which CPS and Carrero should have refunded.

c. On November 13, 2013, Carrero performed acupuncture on patient W.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,025.91, which CPS and Carrero should have refunded.

d. On November 13, 2013, Carrero performed acupuncture on patient M.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,025.75, which CPS and Carrero should have refunded.

e. On November 13, 2013, Dickerson performed acupuncture on patient E.F., for which CPS submitted a claim to Medicare under codes L8680 and 64999 and was paid a total of $1,025.91, which CPS and Dickerson should have refunded.

f. On November 19, 2013, CPS performed acupuncture on patient W.S., for which CPS submitted a claim to the RRB section of Medicare under code L8680 and was paid a total of $1,016.16, which CPS should have refunded.

g. On November 20, 2013, Carrero performed acupuncture on patient W.C., for which CPS submitted a claim to Medicare under code L8680 and was paid a total of $1,016.16, which CPS and Carrero should have refunded.

h. On November 20, 2013, Carrero performed acupuncture on patient M.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.81, which CPS and Carrero should have refunded.

i. On November 20, 2013, Dickerson performed acupuncture on patient D.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.81, which CPS and Dickerson should have refunded.

j. On December 3, 2013, Kroll performed acupuncture on patient E.F., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS and Kroll should have refunded.

k. On December 4, 2013, Dickerson performed acupuncture on patient M.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.81, which CPS and Dickerson should have refunded.

l. On December 4, 2013, Dickerson performed acupuncture on patient W.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.81, which CPS and Dickerson should have refunded.

m. On December 4, 2013, CPS performed acupuncture on patient D.C., for which CPS submitted a claim to Medicare under code L8680 and was paid $1,016.16, which CPS should have refunded.

n. On December 4, 2013, Dickerson performed acupuncture on patient D.C., for which CPS submitted a claim to Medicare under code L8680 and was paid $1,016.16, which CPS and Dickerson should have refunded.

o. On December 5, 2013, Kroll performed acupuncture on patient D.J., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS and Kroll should have refunded.

p. On December 9, 2013, CPS performed acupuncture on patient M.R., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

q. On December 11, 2013, Dickerson performed acupuncture on patient W.C., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.81, which CPS and Dickerson should have refunded.

r. On December 16, 2013, CPS performed acupuncture on patient M.R., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

s. On December 16, 2013, CPS performed acupuncture on patient J.P., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

t. On December 18, 2013, CPS performed acupuncture on patient K.L., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

u. On December 19, 2013, CPS performed acupuncture on patient C.B., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

v. On December 23, 2013, CPS performed acupuncture on patient D.S., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

w. On December 23, 2013, CPS performed acupuncture on patient J.S., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

x. On December 30, 2013, CPS performed acupuncture on patient D.S., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

y. On December 31, 2013, CPS performed acupuncture on patient J.P., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,027.64, which CPS should have refunded.

z. On January 3, 2014, CPS performed acupuncture on patient B.C., for which CPS submitted a claim to Medicare under code L8680 and was paid $1,026.31, which CPS should have refunded.

aa. On January 3, 2014, CPS performed acupuncture on patient P.D., for which CPS submitted a claim to Medicare under code L8680 and was paid $1,026.31, which CPS should have refunded.

bb. On January 7, 2014, Kroll performed acupuncture on patient D.J., for which CPS submitted a claim to Medicare under code L8680 and was paid $1,026.31, which CPS and Kroll should have refunded.

cc. On January 14, 2014, Arney performed acupuncture on patient M.B., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,038.07, which CPS should have refunded.

dd. On January 16, 2014, CPS performed acupuncture on patient R.H., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,038.07, which CPS should have refunded.

ee. On January 17, 2014, CPS performed acupuncture on patient P.D., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,038.07, which CPS should have refunded.

ff. On January 31, 2014, CPS performed acupuncture on patient P.D., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,038.07, which CPS should have refunded.

gg. On February 27, 2014, CPS performed acupuncture on patient J.B. for which CPS submitted a claim to CHAMPVA seeking payment under codes L8680 and 64999 and was paid a total of $5,404.79, which CPS should have refunded.

hh. On March 6, 2014, CPS performed acupuncture on patient J.B. for which CPS submitted a claim to TRICARE seeking payment under codes L8680 and 64550 and was paid a total of $264.77, which CPS should have refunded.

ii. On March 13, 2014, CPS performed acupuncture on patient D.R., for which CPS submitted a claim to Medicare under codes L8680 and 64550 and was paid a total of $1,038.07, which CPS should have refunded.

jj. On March 19, 2014, Carrero performed acupuncture on patients G.P. and J.R. for which CPS submitted a claim to Medicare seeking payment under code L8680 and was paid $1,026.31 on each, which CPS and Carrero should have refunded.

331. On August 4, 2014, the P-Stim overpayment issue was presented to Davis. It was also addressed in an August 5, 2014 Compliance Committee Meeting, during which "it was unanimously agreed the reimbursement was appropriate for these accounts."

332. Thereafter, per an August 12, 2014 email, CPS made the decision, apparently at Davis's insistence, not to refund the Federal Health Care Programs or TennCare for any of the overpayments.

333. The documentation is clear that CPS was fully aware of these improper billings, for which it had sixty days to refund Medicare and knowingly failed to do so, which decision was confirmed by Davis and, upon information and belief, CPS's Board of Directors.

334. In addition, even though CPS claimed that it would cease billing under L8680 in any capacity, it submitted five claims for services rendered after March 31, 2014, which also were fraudulent claims that resulted in the overpayment of $7,535.75 from Medicare. Of this amount,

Kroll was listed as the rendering provider for two claims submitted under L8680, for which CPS was paid a total of $5,814.48.

D. Additional Unlawful Conduct Attributable To Kroll

335. Kroll was the "model" provider for CPS from the beginning. Kroll oversaw the development and implementation of CPS's policies and trained new providers, as well as those providers who did not correctly capture revenues per patient or were engaging in improper billing. When Muench joined in 2011, he was told that it would be helpful to shadow Kroll to learn about the treatment options he offered his patients.

336. Yet, behind the scenes, Kroll was acting in his own self-interest.

337. For example, in March 2009, Kroll entered into an independent contractor letter agreement with Debra Powell Reed, the sole owner of Gateway EMG, LLC, whereby CPS would pay Ms. Reed 50 percent of its net proceeds for the performance of EMG testing and nerve conduction studies ("NCS") on its patients.

338. However, EMG testing is only reimbursable by Medicaid/TennCare if the physician actually reviews the test on site, in real time. But CPS physicians, including Kroll, never reviewed the tests on site, as they were performed offsite through Gateway. CPS never disclosed this contract to the Federal Health Care Programs or TennCare.

339. Kroll was responsible for CPS fraudulently filing claims for EMG testing under CPT codes 95800-95887, for which Medicaid/TennCare paid CPS $224,103.00. Similarly, Kroll was responsible for CPS fraudulently filing claims to Medicaid/TennCare for NCS under CPT codes 95900-95913, for which Medicaid/TennCare paid CPS $344,483.00.

340. Kroll also had an agreement with Ascend Medical Group, LLC ("Ascend"), dated January 1, 2010, which was owned by Amy Davis, the wife of John Davis. Pursuant to that

agreement, Kroll was supposed to act as the supervising physician over nurse practitioners at Ascend, for which he was paid $2,000.00 per month.

341. However, Kroll did not actively supervise the treatment of any Ascend patients by nurse practitioners. Instead, he referred CPS patients to Ascend for purported psychological evaluations for, among other things, clearance to receive pain pumps for which Kroll then would bill the Federal Health Care Programs.

342. While Kroll reaped the benefits of his unlawful side agreements, he continued to fraudulently bill the Federal Health Care Programs and TennCare for thousands of claims, including when he did not personally treat the patient or supervise the provider who did.

343. In many cases, fraudulent claims were submitted to the Federal Health Care Programs and TennCare with Kroll listed as the Rendering Provider for patients who (a) were located in other parts of the country and physically could not have been seen in any CPS office, (b) were seen by mid-levels or unlicensed/un-credentialed providers instead of Kroll, and (c) purportedly received treatment when Kroll was not at any CPS facility.

344. For CPS to submit a claim for payment to the Federal Health Care Programs through eCW, the Rendering Provider must lock the record. Further, eCW defaulted to the Rendering Provider based on the provider who locked the note.

345. As explained in an October 3, 2016 internal email, Kroll was often listed as the Rendering Provider in eCW when appointments were scheduled in clinics where he treated patients, regardless of whether he actually saw that patient. In addition, Kroll's name was input into CPS's eCW system as the default Rendering Provider for all testing performed at CPS's laboratory. As a result, Kroll is listed as the Rendering Provider for claims relating to patients seen by other providers, including providers in other states.

346. Because claims could not be submitted under Kroll's NPI without either Kroll or someone he provided with his password information having locked the records, Kroll knew or should have known that he was listed as the Rendering Provider on claims for patient treatment and services that he did not render.

347. Regardless of whether Kroll was responsible for the treatment of the patients for whom he was listed as the Rendering Provider, he often was credited for the revenues CPS collected from the UDS when Davis calculated his compensation. Because he profited from the submission of these false claims, Kroll also had reason to know about the conduct.

348. Davis, Dickerson and Carrero also were aware of this unlawful conduct. On June 4, 2015, Dickerson noted that all patients in the Hendersonville office were listed under Kroll's name.

349. On September 14, 2016, Dickerson emailed Davis, with a copy to Carrero, that the iPad tests for his patients were being assigned to Kroll. He questioned what the "ramifications" were for this. Dickerson also later noted that although Kroll was listed as the rendering physician on the iPad tests, Dickerson was listed on the UDS. He followed up by sending Davis three patient names so that he could address the billing issues. Upon information and belief, neither Davis nor the Owners took any action to correct the unlawful practice of billing under Kroll's NPI for patients he did not treat.

350. To ascertain the full extent of damages for these false submissions, each patient record must be reviewed to determine whether the patient actually was treated by Kroll. However, the United States has been able to isolate a distinct time period during which Kroll could not have treated patients and yet billed the Federal Health Care Programs for his services.

351. Specifically, during a trip Kroll took to Italy from May 21 to 31, 2017, CPS submitted 2,537 claims for services rendered with 4,041 claim lines, which listed Kroll as the Rendering Provider and for which Medicare paid CPS a total of $347,984.67. Because of these fraudulent claims, Kroll's billing privileges with Medicare have been revoked.

352. In particular, CPS submitted a claim for patient L.W. who was seen on May 24, 2017 for an established patient office visit (CPT code 99214), which included electronic analysis reprogramming and refill of a spinal canal drug infusion pump (CPT code 62370) and ultrasonic guidance imaging supervision and interpretation for insertion of a needle (CPT code 76942), with Kroll listed as the Rendering Provider, for which Medicare paid CPS a total of $216.26.

353. CPS also submitted a claim for patient S.C., who was seen on May 24, 2017 for initial hospital inpatient care that typically lasts thirty minutes (CPT code 99221), with Kroll listed as the Rendering Provider, for which Medicare paid CPS $76.07.

354. In addition, CPS submitted a claim for patient J.M., who was seen on May 24, 2017 for two types of injections (CPT codes 27096 and J3301) and low osmolar contrast (CPT code Q9966), with Kroll listed as the Rendering Provider, for which Medicare paid CPS a total of $122.06.

355. CPS also submitted a claim for patient D.O., who was seen on May 24, 2017 for chronic care management services occurring twenty minutes per month (CPT code 99490), with Kroll listed as the Rendering Provider, for which Medicare paid CPS $31.43.

356. The majority of the remaining claims submitted when Kroll was out of the country during May of 2017 relate to UDS. For many of these claims, the patients have addresses that are in North Carolina, Virginia, Ohio, Indiana and Mississippi. Even if Kroll was in the country (and he was not), he could not possibly have seen patients in this many different states, and certainly

not on the same day. These claims are illustrative of CPS's practice of submitting UDS claims with Kroll as the Rendering Provider, regardless of whether he treated the patient.

357. Significantly, because Kroll was compensated based on 100 percent of his net revenues, he unjustly received the financial benefit for all of these false claims.

358. Notably, Kroll never made any complaints to the Federal Health Care Programs or TennCare that his NPI number was compromised.

359. Even though the other Owners noted that Kroll could not have possibly seen the number of patients his claims reflected, they failed to take any action to cease the submission of these false claims or to notify the Federal Health Care Programs of the issue.

360. Providing false information on claims to the Federal Health Care Programs is a violation of the FCA.

361. Providing false information on claims to TennCare is a violation of the TMFCA.

362. Moreover, to the extent the provider was a mid-level, by submitting claims under Kroll, CPS received an overpayment, as Medicare pays more for claims submitted by physicians than it does by mid-levels.

363. Had the Federal Health Care programs or TennCare known that Kroll was falsely submitting claims under his NPI, they would have denied payment for these claims.

E. <u>The Owners Knew Or Should Have Known About The Unlawful Conduct</u>

364. The Owners cannot claim that they were unaware of the fraudulent conduct at issue. The Owners themselves submitted false claims for non-reimbursable specimen validity, genetic and iPad testing, and acupuncture, as well as medically unnecessary UDS.

365. The Owners were aware of the ZPIC audit.

366. The Owners either participated in, or turned a blind eye to, this unlawful conduct for years, as they reaped the financial benefits of the standing order for urine drug testing and the bonus policy tied to testing and ancillary services.

367. CPS went from being reimbursed under $3 million by Medicare in 2011 to almost $35 million in 2014.

368. CPS paid the Owners (and the minority owners) a total of over $18 million in both 2013 and 2014, close to $9 million in 2015, over $2.8 million in 2016, and over $10.5 million in 2017.

369. The amounts for 2015 and 2016 are lower because the Owners had agreed to voluntarily reduce their compensation when CPS was dealing with the ZPIC overpayment. As stated at the January 5, 2016 meeting of the Board of Directors of CPS, because of "the financial uncertainty related to the Medicare withholding from the ZPIC audit and due to significant rate cuts to laboratory reimbursements," it was decided to withhold 25 percent of monthly ownership compensation payments.

370. These deficits were made up through catch up payments that CPS paid to the Owners in 2017.

371. CPS paid Carrero $1,935,588.30 in 2013, $1,693,134.30 in 2014, $766,139.98 in 2015, $294,049.72 in 2016 and $1,688,203.27 in 2017.

372. Upon information and belief, Dickerson would have been paid similarly to Carrero, but Kroll would have received almost quadruple of what Carrero was paid based on the payment CPS received from Kroll's claims to the Federal Health Care Programs.

373. The Owners cannot distance themselves from the unlawful conduct at CPS by claiming that the responsibility lies with Davis.

374. The Owners failed to take any steps to stop Davis from engaging in unlawful conduct and even agreed to compensate him for the profits that CPS made from the submission of all of these false claims. In fact, CPS, with the approval of the Owners, entered into a revised Employment Agreement with Davis, dated January 1, 2014, whereby he received even further financial compensation to reward him for his wrongdoing, with a salary of $180,000 and quarterly bonuses that amounted to seven percent of CPS's net profits, as well as a Discretionary Bonus, in addition to five weeks of paid vacation.

375. Dickerson and Carrero may have at times voiced their concerns over Davis's conduct, yet they failed to take action against him – choosing instead to keep the status quo of money flowing into their bank accounts.

376. On February 11, 2016, CPS's Board of Directors approved an amendment to Davis's employment agreement, which converted the three percent Discretionary Bonus to a performance based bonus, thereby increasing Davis's performance based bonus from to ten percent and removing any ability of the Board to control his overall compensation.

377. Tellingly, Dickerson had no qualms with voicing his concerns when he believed that CPS needed a person in charge of "quality management and quality control." In a September 28, 2012 email, he expressed that an RN would be best suited for this "and nothing else would be advisable. Now." Yet, when it came to stopping Davis from incentivizing employees to submit false claims, he failed to take action.

378. In addition, Kroll had knowledge of the daily activities of CPS providers as he was the Chief Medical Officer, was directly involved in addressing the problems identified through the ZPIC audit, a member of the Compliance Committee and on countless emails about billing issues at CPS.

VII. CPS'S DISSOLUTION AND FRAUDULENT CONVEYANCES TO THE OWNERS IN VIOLATION OF THE FEDERAL PRIORITY STATUTE

379. After the UDS scheme imploded with an initial finding of a $27 million overpayment and while CPS engaged in the process of appealing the decision, CPS's cash flow was compromised. In or about February 2016, Davis made the decision to terminate over 80 employees at the Gallatin Operations Center.

380. On or about June 29, 2016, Davis emailed CPS employees that because of changes in reimbursement, regulatory impacts and increased competition, CPS made a decision to close thirteen offices over the next nine months.

381. Davis, who had expanded CPS rapidly with the hope of finding a suitor to purchase the company, now found it impossible to do so.

382. On or about June 2, 2017, Davis turned in a resignation letter to the Board of Directors for CPS.

383. CPS was placed on a partial payment suspension, effective August 21, 2017, whereby it no longer could receive Medicare reimbursement from Novitas.

384. Throughout 2017 and 2018, Kroll, in particular, continued to try to utilize the UDS process to capture revenues, but it was not enough to keep CPS afloat.

385. Between the payment suspension and Palmetto's requirements for reimbursement of UDs claims, CPS could no longer continue its excessive and medically unnecessary testing. Thus, CPS no longer was receiving millions of dollars in revenues from the Federal Health Care Programs and TennCare, which it needed to continue to operate the business and compensate the physicians and other employees.

386. On April 4, 2018, Davis was indicted for his role in a DME kickback scheme. (This conduct is not included as a part of the wrongdoing alleged in this civil action.)

387. In the end, CPS could not survive, and the Owners voted to begin the process of dissolution in July 2018.

388. Yet, throughout 2017 and 2018, the Owners continued to pay themselves with profits from CPS, including from reimbursements from the Federal Health Care Programs and TennCare that were based on false submissions.

389. At a July 17, 2017 Board of Directors meeting, the Owners voted not to withhold any amounts from the payments CPS made to the Owners. As a result, the Owners took out as much money from CPS as possible from July 2017 until it ceased operating in or about May of 2018.

390. The Owners received $550,338.09 as compensation for July 2017, with $226,146.40 to Kroll, $125,845.40 to Dickerson and $103,944.85 to Carrero.

391. For August 2017 collections, the Owners received $552,025.97, with Kroll taking $229,958.94, Dickerson earning $109,107.40 and Carrero receiving $96,074.00.

392. For September 2017 collections, the Owners received $414,300.12, with Kroll taking $156,343.76, Dickerson earning $78,858.52 and Carrero receiving $77,292.82.

393. The Owners received $427,340.90 as compensation for October 2017, with $145,466.74 to Kroll, $99,046.48 to Dickerson and $92,866.33 to Carrero.

394. For November 2017 collections, the Owners received $431,803.09, with Kroll taking $157,078.09, Dickerson earning $101,275.53 and Carrero receiving $87,682.77.

395. For December 2017 collections, the Owners received $332,226.02, with Kroll taking $111,410.07, Dickerson earning $71,018.81 and Carrero receiving $84,181.40.

396. The Owners received $324,843.94 as compensation for January 2018, with $111,599.01 to Kroll, $63,064.34 to Dickerson and $58,586.35 to Carrero.

397. For February 2018, they received another $368,915.43, with $141,535.91 for Kroll, $62,612.99 to Dickerson and $83,478.33 for Carrero.

398. For March 2018, they received another $241,536.15, with $84,819.29 for Kroll, $45,860.40 to Dickerson and $55,893.56 for Carrero.

399. For April 2018, they received $197,143.02, with $87,170.05 for Kroll, $24,650.73 for Dickerson and $39,394.51 for Carrero.

400. Moreover, in 2018, the Owners sold off various CPS clinics and assets for over $3.4 million.

401. At the time of the asset sales and voluntary transfers, CPS was aware that it was insolvent and that the United States had claims against it, which are the subject of this action.

402. Yet, upon information and belief, CPS did not place any funds in escrow or preserve the proceeds from the asset transfers for the benefit of the United States.

403. CPS's conduct, as well as that of its Owners, representatives and agents acting on its behalf, violates 31 U.S.C. § 3713 (the "Federal Priority Statute").

VIII. DEFENDANTS CAUSED FRAUDULENT FORMS TO BE SUBMITTED

404. Defendants were fully aware of the requirements for participation in the Federal Health Care Programs and TennCare.

405. The Owners each were enrolled in the Federal Health Care Programs and TennCare during the relevant time period.

406. Davis also was aware of Medicare requirements throughout the relevant time period, as he had submitted and signed a Medicare Enrollment Application with Cahaba, dated August 3, 2011.

407. In March 2017, Davis also executed the contract with TriWest that allowed CPS to be enrolled in the Choice Program.

408. Upon information and belief, Smith also was enrolled in Medicare, even though he was not billing.

409. CPS billed the Federal Health Care Programs and TennCare under NPI 1104854124.

410. The Medicare Enrollment Agreements for CPS, the Owners and Smith contained the following certification: "I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment."

411. By executing these EDI Agreements, CPS, the Owners and Smith also acknowledged that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law."

412. Dickerson, an original founder of CPS, re-assigned his Medicare benefits under his NPI 1366485328 to CPS on October 2, 2000 and revalidated his enrollment information, upon information and belief, every three years thereafter.

413. Carrero re-assigned his Medicare benefits under his NPI 1417997990 to CPS on June 1, 2004 and revalidated his enrollment information, upon information and belief, every three years thereafter.

414. Kroll re-assigned his Medicare benefits under his NPI 1124020011 to CPS on August 1, 2006 and revalidated his enrollment information, upon information and belief, every three years thereafter.

415. Defendants submitted, or caused the submission of, the claims to the Federal Health Care Programs and TennCare using CPS's NPI number. Thus, the ultimate reimbursement for claims went directly to the CPS, rather than to the individual providers. Because the Owners, Davis and Smith were paid from CPS's revenues, which in large part consisted of reimbursement of false claims submitted to the Federal Health Care Programs and TennCare, the Owners, Davis and Smith profited from CPS's fraudulent submission of claims.

416. The Owners, Davis and Smith also were aware that they could not falsify claims. Indeed, during the relevant time period, the Owners and Davis attended compliance training and certified that they understood their legal obligations.

417. Further, CPS's internal compliance policies and Code of Conduct stated that submission of claims to the Federal Health Care Programs "must be complete and accurate and comply with legal requirements." It further notes, that claims "must reflect reasonable and necessary services ordered…." In addition, CPS encouraged self-reporting of wrongdoing and indicated that it would "take remedial steps to correct the problem and prevent the overpayment from recurring."

418. Yet, Defendants failed to abide by CPS's internal policies, the requirements of the Federal Health Care Programs, TennCare or any other applicable law or regulation.

IX. THE OWNERS' PROFITS FROM AND LIABILITY FOR CPS'S FRAUD

419. The Owners profited directly from CPS's submission of false claims, false statements, and failure to refund the overpayments for non-reimbursable acupuncture to the Federal Health Care Programs and TennCare.

420. Medicare paid CPS over $2.7 million for claims submitted in 2011.

421. Medicare paid CPS almost $6 million for claims submitted in 2012.

422. Medicare paid CPS over $17.5 million for claims submitted in 2013.

423. Medicare paid CPS over $34.5 million for claims submitted in 2014.

424. Medicare paid CPS over $24.5 million for claims submitted in 2015.

425. Medicare paid CPS almost $18 million for claims submitted in 2016.

426. Medicare paid CPS over $40 million for claims submitted in 2017, after the United States served a Civil Investigative Demand on CPS.

427. Medicare paid CPS over $10 million for claims submitted in 2018.

428. In total, Medicare paid CPS over $150 million from 2011 to 2018, a large part of which was related to UDS.

429. In total, TennCare paid CPS over $32.5 million from 2011 to 2018.

430. The relevant Operating Agreement for CPS does not contain any carve out for the Owners in the event that they commit fraud.

431. The Owners are liable for their own fraudulent conduct and/or omissions.

432. As detailed above, the Owners also knew or should have known about the extensive fraudulent conduct at CPS and failed to take any action to stop such conduct or to notify the Federal Health Care Programs or TennCare of the wrongdoing.

433. Because the Owners engaged in the same wrongful conduct as CPS as a whole, they are liable for all wrongful acts and/or omissions attributable to CPS.

COUNT I

FCA and TMFCA: Presentation of False Claims
(31 U.S.C. § 3729(a)(1) and (a)(1)(A); Tenn. Code Ann. § 71-5-182(a)(1)(A))

434. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

435. As detailed above, Defendants presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the United States and Tennessee, including claims for reimbursement by the Federal Health Care Programs and TennCare that were false and fraudulent because, among other things, they (i) were for services for which the Federal Health Care Programs and TennCare do not reimburse; (ii) were not medically necessary; and/or (iii) contained false information as to the Rendering Provider.

436. As detailed above, the Federal Health Care Programs and TennCare would not otherwise have paid for these false and fraudulent claims.

437. Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

438. Defendants are liable to the United States and Tennessee for damages in an amount to be determined at trial, but not less than $25 million in single damages, trebled, as well as a minimum civil penalty to the United States of $5,500 and up to a maximum penalty of $11,000 for each false claim presented or caused to be presented prior to November 2, 2015, and a minimum civil penalty of $11,181 to a maximum penalty of $22,363 for claims after November 2, 2015 to the present, and a civil penalty to Tennessee of $5,000 to $25,000 for each violation.

COUNT II

FCA and TMFCA: Using False Statements to Get False Claims Paid
(31 U.S.C. § 3729(a)(1)(B); Tenn. Code Ann. § 71-5-182(a)(1)(B))

439. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

440. As detailed above, Defendants made, used, or caused to be made or used, false records or statements, which included the false certifications and representations on forms CMS 1500, as well as the EDI enrollment and applications, to obtain approval for and payment by the United States and Tennessee for false or fraudulent claims as detailed above.

441. Defendants' false certifications and representations were made for the purpose of ensuring that the Federal Health Care Programs and TennCare paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

442. The false certifications and representations made or caused to be made by Defendants were material to the payment of the false claims by the United States and Tennessee.

443. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

444. Defendants are liable to the United States and Tennessee for damages in an amount to be determined at trial, but not less than $25 million, trebled, as well as a minimum civil penalty to the United States of $5,500 and up to a maximum penalty of $11,000 for each false claim presented or caused to be presented prior to November 2, 2015, and a minimum civil penalty of $11,181 to a maximum penalty of $22,363 for claims after November 2, 2015 to the present, and a civil penalty to Tennessee of $5,000 to $25,000 for each violation.

COUNT III

FCA and TMFCA: False Record Material to Obligation to Pay
(31 .S.C. § 3729(a)(1)(G); Tenn. Code Ann. § 71-5-182(a)(1)(D))

445. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

446. As detailed above, Defendants made, used, or caused to be made or used, false records or statements material to obligations to pay or transmit money to the United States and Tennessee, or concealed, improperly avoided or decreased obligations to pay or transmit money to the United States.

447. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

448. Defendants are liable to the United States and Tennessee for damages in an amount to be determined at trial, but not less than $25 million, trebled, as well as a minimum civil penalty of $5,500 and up to a maximum penalty of $11,000 for each false claim presented or caused to be presented prior to November 2, 2015, and a minimum civil penalty to the United States of $11,181 to a maximum penalty of $22,363 for claims after November 2, 2015 to the present, and a civil penalty to Tennessee of $5,000 to $25,000 for each violation.

COUNT IV

FCA and TMFCA: Reverse False Claim- Against CPS, Davis and the Owners
(31 U.S.C. § 3729(a)(7); Tenn. Code Ann. § 71-5-182(a)(1)(D))

449. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

450. CPS, Davis and the Owners made or used, or caused to be made or used, false records and statements to conceal, avoid, or decrease an obligation to pay or transmit money to the

United States and Tennessee with respect to claims submitted for acupuncture being billed fraudulently in violation of 31 U.S.C. § 3729(a)(7) and Tenn. Code Ann. § 71-5-182(a)(1)(D).

451. Said concealment and avoidance was done with actual knowledge of the refund or payment obligations, or with reckless disregard or in deliberate ignorance of these obligations.

452. Because of the unlawful conduct of CPS, Davis and the Owners, the United States and Tennessee are entitled to damages in an amount to be determined at trial, but not less than $136,000, trebled, as well as a minimum civil penalty to the United States of $5,500 and up to a maximum penalty of $11,000 for each false claim presented or caused to be presented prior to November 2, 2015, and a minimum civil penalty of $11,181 to a maximum penalty of $22,363 for claims after November 2, 2015 to the present, and a civil penalty to Tennessee of $5,000 to $25,000 for each violation.)

COUNT V

Violation of the Federal Priority Statute and Fraudulent Conveyances
(31 U.S.C. § 3713 *et seq.*)

453. The United States repeats and realleges all preceding paragraphs of this Complaint as if fully set forth herein.

454. During the relevant time period, CPS was insolvent and not in bankruptcy.

455. During the relevant time period, CPS and the Owners were aware that the United States had claims against CPS and the Owners.

456. Despite this knowledge, CPS continued to pay profits to the Owners and voluntarily assigned its assets to third parties and/or committed an act of bankruptcy.

457. Pursuant to the Federal Priority Statute, the United States is entitled to payment of claims over other creditors.

458. CPS's Owners and agents caused CPS to pay debts to others before the United States, including to the Owners.

459. CPS's representatives and agents, including the Owners, are liable to the extent of the payments made by and transfers received from CPS to which the United States otherwise would have been entitled to and had priority of payment over other creditors of CPS.

460. The Owners are personally liable for paying themselves and other creditors before satisfying a debt owed to the United States or providing for funds to be placed into escrow to protect the amount of the United States' claim.

461. The Owners are liable to the United States for the amount of the fraudulent conveyances and then known claims in an amount to be determined at trial, but not less than $3 million, as well as the amount of profits the Owners received from CPS in 2017 and 2018.

COUNT VI
Payment by Mistake

462. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

463. The United States and Tennessee paid Defendants, either directly or indirectly, for claims submitted by Defendant CPS for services that were (i) not medically necessary; and/or (ii) did not otherwise satisfy the requirements of the Federal Health Care Programs and TennCare, without knowledge of material facts, and under the mistaken belief that Defendants were entitled to receive payment for such claims.

464. The mistaken belief of the United States and Tennessee was material to their decision to pay Defendants on such claims.

465. The United States and Tennessee reasonably relied on the Owners' and CPS's submission of claims that they believed were accurate, complete, and truthful, in accordance with the express requirements of the Federal Health Care Programs and TennCare.

466. The United States and Tennessee has been damaged as a result of this mistaken payment, and the Owners and CPS are thus liable to account and pay to the United States and Tennessee such amounts, which are to be determined at trial.

COUNT VII

Unjust Enrichment

467. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

468. By retaining monies and profits received from services that were not reimbursable, Defendants retained money that was the property of the Federal Health Care Programs and TennCare, to which they were not entitled.

469. The United States and Tennessee seek the recovery of all funds paid by the Federal Health Care Programs and TennCare by which Defendants have been unjustly enriched, including profits unlawfully earned from urine and blood testing at CPS's lab, claims for reimbursable psychological testing and acupuncture, and other amounts paid based on claims for services that were medically unnecessary or for services not rendered or not accurately described.

470. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States and Tennessee in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States and Tennessee.

COUNT VIII
Common Law Fraud

471. The United States and Tennessee repeat and reallege all preceding paragraphs of this Complaint as if fully set forth herein.

472. As set forth in detail above, from 2011 through 2018, Defendants made numerous material false statements to the United States and Tennessee to obtain money from the Federal Health Care Programs and TennCare.

473. The Owners and Davis knew or should have known about the fraudulent conduct at CPS.

474. The Owners also failed to tell the Federal Health Care Programs and TennCare about the fraudulent activity at CPS, which was a material omission.

475. Defendants made such material false statements and omissions with the intent that the United States and Tennessee would rely on them in making determinations to pay claims submitted to the Federal Health Care Programs and TennCare.

476. The United States and Tennessee reasonably relied on Defendants' material misrepresentations and omissions.

477. The United States and Tennessee were injured as a result of Defendants' unlawful conduct in an amount to be proven at trial.

PRAYER FOR RELIEF

Wherefore, the United States and Tennessee demand that judgment be entered in their favor and against Defendants jointly and severally as follows:

1) On Counts One, Two, Three and Four against all Defendants for violation of the FCA and TMFCA, with the amount of damages trebled and such penalties as required by law, together with all such further relief as may be just and proper.

2) On Count Five against CPS and the Owners for violation of the Federal Priority Statute and fraudulent conveyances, the amounts CPS and the Owners paid themselves and others who did not have priority over the claims of the United States in an amount not less than $3.4 million, plus the amount of profits the Owners received from CPS in 2017 and 2018, as well as interest, costs and expenses, together with all such further relief as may be just and proper.

3) On Count Six against all Defendants, the amounts the Federal Health Care Programs and TennCare mistakenly paid CPS, and indirectly the Owners, Davis and Smith, to which they were not entitled, plus interest, costs and expenses, together with all such further relief as may be just and proper.

4) On Count Seven against all Defendants, the amount by which Defendants were unjustly enriched or retained monies received from reimbursements paid by the United States and Tennessee to which they were not entitled, plus interest, costs and expenses, together with all such further relief as may be just and proper.

5) On Count Eight for common law fraud against all Defendants, the amounts they fraudulently obtained from the Federal Health Care Programs and TennCare, plus interest, costs, and expenses, together with all such further relief as may be just and proper.

6) All other relief as may be required or authorized by law and in the interests of justice.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States and Tennessee demand a trial by jury on all issues so triable.

Respectfully submitted,

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